

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

_____	x	
	:	
THE CITY OF HUNTINGTON,	:	Civil Action
	:	
Plaintiff,	:	No. 3:17-cv-01362
	:	
v.	:	
	:	
AMERISOURCEBERGEN DRUG	:	
CORPORATION, et al.,	:	
	:	
Defendants.	:	

_____	x	
	:	
CABELL COUNTY COMMISSION,	:	Civil Action
	:	
Plaintiff,	:	No. 3:17-cv-01665
	:	
v.	:	
	:	
AMERISOURCEBERGEN DRUG	:	
CORPORATION, et al.,	:	
	:	
Defendants.	:	

BENCH TRIAL - VOLUME 35
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

JULY 7, 2021

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Proceedings recorded by mechanical stenography;
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1 PROCEEDINGS had before The Honorable David A.
2 Faber, Senior Status Judge, United States District
3 Court, Southern District of West Virginia, in
4 Charleston, West Virginia, on July 7, 2021, at 9:00
5 a.m., as follows:

6 THE COURT: Good morning, everybody. Hope
7 everybody enjoyed the long weekend. Are you ready to call
8 your next witness?

9 MS. MAINIGI: We are, Your Honor. We call Mr. --
10 or Dr. Timothy Deer. He is a standard of care expert, our
11 second and last standard of care expert.

12 THE COURT: You can take the oath here.

13 COURTROOM DEPUTY CLERK: Please state your full
14 name.

15 THE WITNESS: Timothy Ray Deer.

16 COURTROOM DEPUTY CLERK: What was your last name
17 again?

18 THE WITNESS: Deer, D-e-e-r, just like the animal.

19 COURTROOM DEPUTY CLERK: Thank you. Please raise
20 your right hand.

21 **DR. TIMOTHY R. DEER, DEFENSE WITNESS, SWORN**

22 COURTROOM DEPUTY CLERK: Thank you. Please take a
23 seat.

24 THE COURT: Good morning, sir.

25 THE WITNESS: Good morning.

1 MS. MAINIGI:

2 Q. Good morning, Dr. Deer.

3 A. Good morning.

4 Q. Where do you currently live?

5 A. I live in Charleston, West Virginia.

6 Q. And, Dr. Deer, what do you do for a living?

7 A. I'm a physician.

8 Q. What type of physician?

9 A. Anesthesiology and pain medicine.

10 Q. Now, you're obviously here testifying as an expert.
11 What is your field of expertise?

12 A. Pain medicine.

13 Q. And within pain medicine, is there both -- in terms of
14 what your practice is, is there both interventional and
15 non-interventional pain management?

16 A. That's correct. I certainly am known for my work in
17 interventional pain, for the most part, but we also have a
18 multimodal practice where we also have to manage the
19 non-interventional sections, as well.

20 Q. Can you describe for the Court what interventional pain
21 management is?

22 A. So, interventional pain treatment really involves work
23 looking at using minimally invasive techniques, such as
24 intradiscal procedures or interspinous procedures, or
25 peripheral nerve procedures to treat pain in a fashion that

1 really tries to alleviate the need for medication, the need
2 for, you know, any type of medical treatment other than
3 physical therapy and occupational therapy.

4 So, we combine what we do with the TOT and try to get
5 function better. We also sometimes can do things now
6 through small tubes and things where we actually can do
7 surgeries for like spinal stenosis or SI Joint Dysfunction
8 without the need for a large spinal fusion or a large spinal
9 surgery.

10 So, we're actually replacing, much like the
11 cardiovascular stint replaced the bypass, we're replacing a
12 lot of large spine procedures now with methods we've
13 developed over the last 25 years.

14 **Q.** And non-interventional pain management, just to close
15 the loop on that, what is that?

16 **A.** That's a -- non-interventional pain medicine goes from
17 massage therapy, which we do have PT as part of our
18 practice, all the way to medication management, which
19 includes opioid prescribing, as I know, which is the issue
20 in this case. So, obviously, multimodal means you do both
21 and most interventionalists, because we take over referred
22 patients, we end up doing both interventional and
23 non-interventional pain treatment.

24 **Q.** Thank you, Dr. Deer.

25 Let's take a few minutes and walk through your

1 background and qualifications. And I think we made some
2 slides, with your assistance, that illustrates some of your
3 background and qualifications.

4 MS. MAINIGI: Matt, if you could put Demonstrative
5 Slide 1 up, please. Thank you.

6 BY MS. MAINIGI:

7 Q. And, Dr. Deer, is this just a background slide that you
8 helped us create that has pertinent information for you?

9 A. Yes. That summarizes my educational background.

10 Q. Where are you from originally, Dr. Deer?

11 A. Chesapeake, West Virginia.

12 Q. Where did you go to high school?

13 A. East Bank High School.

14 Q. And where did you go to college?

15 A. West Virginia University Tech, where I was a biology
16 and business major.

17 Q. And, now, you went to West Virginia to play football?

18 A. I went to West Virginia Tech to play football. Don
19 Nehlen offered me the walk on, but I couldn't afford to do
20 so, so West Virginia Tech gave me a full scholarship. So,
21 that was a better avenue for me at the time.

22 Q. And how were your grades when you graduated?

23 A. I was summa cum laude.

24 Q. And you went on to medical school, obviously?

25 A. Yes.

1 Q. Where did you go to medical school?

2 A. West Virginia University.

3 Q. And what year did you graduate?

4 A. 1990.

5 Q. And how did you graduate in your class?

6 A. I was first in my class.

7 Q. And then, where did you go on for your residency?

8 A. University of Virginia.

9 Q. And during residency, what was your specialty?

10 A. So, I did my first portion of my internship in internal
11 medicine. And then anesthesiology. And then, I did a
12 clinical fellowship in pain medicine.

13 Q. And where was the clinical fellowship in pain medicine?

14 A. At the University of Virginia. I did all my training
15 there.

16 Q. And when did you finish your fellowship, Dr. Deer?

17 A. End of 1994.

18 Q. Now, after you wrapped up your schooling and your
19 training in 1994, where did you go to practice at that
20 point?

21 A. So, I came back to Charleston, West Virginia, where I
22 practice today.

23 Q. And you began your own practice?

24 A. I did. I -- at the time, I had the opportunity to stay
25 in Charlottesville, Virginia with my mentor, John

1 Rowlingson, but I had -- you know, I had a couple other
2 things bring me back here. So, I decided to come back here
3 and it was a -- I think a very good decision to come here.

4 **Q.** Why did you -- let's pause on that for a minute. Why
5 did you come back to West Virginia and Charleston to
6 practice?

7 **A.** Well, really, two reasons.

8 One is, I'm from here. I love it here.

9 Secondly, you know, that reason goes back to, you know,
10 when I grew up here, my dad and both grandpas were coal
11 miners and I knew people here had a lot of need for
12 treatment.

13 I came home to visit my parents, my wife's parents, and
14 I went to Wal-Mart and watched people walk in and out of
15 Wal-Mart and I realized there was a big need here for what I
16 do.

17 And, secondly, my wife told me I had to come back here.
18 So, that was probably the pressing reason, because she's up
19 Elk River and her parents live there. So --

20 **Q.** Generally a good practice to do what your wife says.

21 **A.** Yeah. Yeah. And so, we're still together. I think
22 that's probably the reason we are. So --

23 **Q.** So, you've been practicing in Charleston for about
24 30 years or so?

25 **A.** 27 years, yeah.

1 Q. And in pain management?

2 A. Correct. I'm board certified in anesthesiology, as
3 well, but I haven't practiced anesthesia since 1996, when I
4 went full-time pain.

5 Q. And where are you practice -- where are you licensed to
6 practice medicine?

7 A. West Virginia; Virginia, where I trained; and Florida,
8 where I -- where I eventually may retire, but maybe not.

9 Q. And you mentioned the board certification. Do you have
10 board certification in anesthesiology; is that right?

11 A. Correct. American Board of Anesthesiology and American
12 Board of Pain Medicine. And then, I'm also -- I have an
13 international certification called RIP, which is required
14 when you practice overseas. So, I do practice doing studies
15 in Germany, Holland and Hong Kong.

16 Q. And what do you do in those jurisdictions?

17 A. So, when a procedure gets done in America, many times
18 the FDA won't approve the initial study until it's been
19 really shown to be safe in other areas. So, I often will
20 work on development of the device, and then I'll go either
21 to Dusseldorf, or to Amsterdam, or Hong Kong to review the
22 device with the surgeons there. And so, that's done in
23 animals and cadavers usually before that. I usually go
24 there to help them learn the technique. And then, once
25 that's done there, the FDA will often approve a multicenter,

1 prospective study. And then, we'll do that usually at our
2 center, along with the Cleveland Clinic and the Mayo Clinic
3 and some colleagues.

4 **Q.** So, let's talk a little bit about pain management, Dr.
5 Deer. Describe for me just at a high level how serious pain
6 can affect a patient's life.

7 **A.** Well, I know, in this trial, both sides of you see
8 that. Certainly, if you -- you know, as an example, if you
9 have a small business and you're doing well and then you
10 have a herniated disc and you get back surgery, about, you
11 know, 80 percent of the time, you'll do fairly well, but
12 20 percent of the time, you'll get scar tissue or nerve
13 damage and you'll have severe chronic pain that doesn't go
14 away.

15 And then, a lot of times what happens is, you can't
16 work anymore. So, if you have a small business, it will
17 close.

18 It causes a lot of problems with the family. So, you
19 get divorced. Your kids are not happy.

20 And then, you know, if you had employees, they get laid
21 off.

22 And so, it becomes a real, you know, impact on both
23 your pain, your suffering, but also, on your family and
24 society around you.

25 And then, the cost of that patient's care, obviously,

1 is pretty astronomical over time.

2 **Q.** So, we talked about why you came back to West Virginia
3 but what made you decide in the first place to specialize in
4 pain management?

5 **A.** Well, I went to UVA, actually, to do cardiology because
6 Bill Carter and staff were my mentors here in Charleston and
7 they were doing something called angioplasty, which were
8 thought to be radical. You know, they thought Dr. Warren
9 was crazy. And then, they were thinking about a stint,
10 which I thought was really crazy.

11 And when I got to Charlottesville, I really fell in
12 love with the ICU. I did neuro-ICU work for about four
13 months during my residency.

14 At one point, I decided early on that I wanted to go
15 and do transplant anesthesia. So, I switched to
16 anesthesiology to do that. But then, I realized you have to
17 live in a big city to do transplant anesthesia. And, as I
18 learned about in interventional pain, UVA was the second
19 center in the country, I believe, after University of
20 Washington, to have a full-fledged center. So, I learned
21 about that technique.

22 And I had a patient on my rotation in my second year of
23 residency who had lung cancer metastasize to her spine and
24 we put a tunneled catheter in around the spine and she died
25 very comfortably four weeks later. And so, when I saw that,

1 I said this is the future and, you know, using techniques to
2 help people's pain, rather than other options. So, that
3 really -- that's what engaged me.

4 **Q.** So, let's shift over to talk about this practice that
5 you've built here. What's the practice called?

6 **A.** Spine & Nerve Centers of the Virginias.

7 **Q.** And is it based right here in Charleston?

8 **A.** Well, we have -- it's where our main office is, is
9 Charleston. We have a care center for Southern West
10 Virginia, Kentucky, Virginia. But we also have offices in
11 other locations. We have an office in Logan County at Logan
12 General, Boone County at Boone Memorial, Teays Valley at
13 CAMC, and at CAMC here in Charleston.

14 **Q.** So, let me ask you about the nature of your practice.
15 Do you treat patients with acute pain, cancer pain and
16 chronic non-cancer pain?

17 **A.** So, let me break down those buckets for the Court. So,
18 acute pain -- now, let's say, for example, Lord forbid, that
19 today you injured yourself and three or four weeks later,
20 your pain was severe and you needed a nerve procedure. We
21 may treat you for that, you know, with some sort of simple
22 injection, PT, and you may get better.

23 And so, most people don't need us for that and get
24 better on their own, but we do treat those people. Then,
25 you have chronic cancer pain, which is a big part of my

1 practice. You know, it's people who, let's say you had a
2 cancer that grew from your ovary into your spine and now
3 your nerve is getting compressed. You know, medication
4 doesn't help that type of pain usually much. So, the
5 oncologist would have someone on a large dose of opioids.
6 They aren't getting better. They'll send them to see us.
7 We'll convert them over to something like a fentanyl patch
8 --

9 COURT REPORTER: Could you slow down just a little
10 bit, please?

11 THE WITNESS: Oh, I'm sorry.

12 COURT REPORTER: That's okay.

13 THE WITNESS: I have this problem with speaking
14 fast even though I'm from here. So, please just tell me.

15 COURT REPORTER: Thank you.

16 THE WITNESS: I apologize for that.

17 COURT REPORTER: Thank you.

18 THE WITNESS: So, we'll switch them over to
19 something like a patch temporarily and then try to get a
20 device in around the nerve. So, that's cancer pain.

21 We do -- also, we do procedures where we put cement
22 around bones that are fractured from the cancer. So, that's
23 kind of our main focus.

24 And then, non-cancer is mostly spine for us, but we
25 take referrals only and, usually, they're one of three

1 groups of people.

2 One is local people who usually have been treated by
3 someone in Southern West Virginia, Central West Virginia,
4 usually a family practice. And usually for, unfortunately,
5 it used to be three or four years. Now, it's down to about
6 six months. So, it's really improved. But then, they'll
7 eventually send them to see us. If their opioid dose gets
8 too high or they aren't responding, we'll take them over and
9 then we'll try to do things to get them off of or reduce the
10 opioids and improve their function.

11 Group two is people who get sent to me specifically for
12 a procedure. For example, you know, if a doctor at St.
13 Mary's doesn't do a spinous spacer, he may send me that
14 patient for an interspinous spacer and then I'll send them
15 back. So, those are very specific procedural things.

16 I do a lot of revision surgeries after implants from
17 around the East Coast.

18 And then, we have an international referral base.
19 Usually, about five to ten patients a year will come from
20 international areas before COVID. Since COVID, we've had no
21 international patients at all. I don't know if that will
22 change, but in the past, we've had several international
23 patients for very specific procedures and then they've gone
24 back.

25 **Q.** And during the course of your practice, Dr. Deer, do

1 you also sometimes prescribe opioid pain medications?

2 **A.** We do often prescribe opioids. We receive patients in
3 referral and, when you receive a patient in referral, you
4 take over their care. And then, when we take over their
5 care, if they're on a high dose of opioid, we take that
6 over, but then the reason people get sent to us normally is
7 that the patient themselves want to find other options or
8 the family doctor gets uncomfortable. So, we -- we will
9 take those folks over.

10 And I think we'll see, as we talk, it's gotten a lot
11 better in the last years with new legislation, but once we
12 take them over, it takes us anywhere from three months to
13 three years to get them reduced on their opioid dose. But
14 80-85 percent of the time, our data, which our WVU med
15 students do frequently for us, we get them either off all
16 their opioids or at least half of their opioids. That's
17 been our experience.

18 **Q.** And do you have others that work in your practice with
19 you, other doctors?

20 **A.** We have three physicians and four nurse practitioners
21 in the practice.

22 **Q.** And you mentioned that a component, a big component of
23 your practice, is referral base. Can you just explain that
24 to me?

25 **A.** So, you can't come see us if you want treatment. I

1 think, if you look at appropriate prescribing and things of
2 that nature, we like to make sure that people try physical
3 therapy and other things.

4 So, you see your family doctor. You know, you have a
5 herniation, you have stenosis, you have -- and they treat
6 you however they treat you; oftentimes, it's been opioids.

7 And then, over time, they will send you to see us.
8 We'll review records. If we think we may be able to help
9 you, we'll accept your care, we'll take over your care,
10 we'll take care of you.

11 But referral base means we don't take patients -- you
12 can't call the office and make an appointment. You have to
13 have a referral to see us. We screen the records and see if
14 we have some innovation that might help you.

15 **Q.** Now, Dr. Deer, are you affiliated with any of the local
16 hospitals?

17 **A.** We are.

18 **Q.** Which ones?

19 **A.** Thomas Hospital System, where I'm -- where I spend most
20 of my time, Charleston Area Medical Center, Boone Memorial
21 Hospital, Logan General Hospital. And then, we're
22 affiliated with WVU, but we don't practice at WVU. We just
23 have their students.

24 **Q.** And did you hold the Medical Director title for a
25 period of time at both St. Francis and then Charleston Area

1 Medical Center?

2 **A.** I have. So, CAMC asked me to be their Medical Director
3 of Pain when they were converting the Joint Commission
4 requirements back in turn of the century. And then, since
5 that time, I've been serving as Medical Director of Thomas
6 Health Systems, St. Francis and Thomas.

7 **Q.** And was there a time when you came to also handle the
8 majority of the patients that were suffering from cancer
9 pain at the CAMC Cancer Treatment Center?

10 **A.** We've had an office at Memorial for many years where
11 it's primarily cancer treatment. So, yes, that's true. We
12 also have seen a lot of cancer patients from Thomas, too,
13 Dr. Jonathan Pauley (phonetic), Dr. Shah.

14 And then, from other areas of the state when cancer
15 particularly has metastasized, when somebody has a lot of
16 pain before they go to Hospice. Someone may live a long
17 time before they need Hospice and we get usually called in
18 when someone is miserable but hasn't really been to the
19 point of going to Hospice yet. That's kind of where we fall
20 with those patients.

21 **Q.** At this point in your practice, do you have any idea,
22 Dr. Deer, about how many patients in total you normally have
23 at any given time?

24 **A.** We have about 4,000 patients at a time we follow as a
25 group. And that can range from someone we see every few

1 weeks for some reason or someone we see every six to
2 twelve months. So, it really, you know, varies, but about
3 4,000 active patients at any one time. And that comes and
4 goes based on securing acute pain, or recent pain, or people
5 passing away with terminal disease.

6 **Q.** And is there any other practice in this area that does
7 what you do?

8 **A.** We're the biggest practice in West Virginia, I think,
9 for pain. We're the only one in this part of the state.
10 Huntington has a few pain specialists, though, at
11 Cabell-Huntington and St. Mary's that treat pain, as well.
12 WVU has a pain division, Dr. Vaglianti's division. And
13 there's a few, you know, that do injections around the
14 state, but as far as comprehensive care, we are the largest
15 practice in the state, I believe.

16 **Q.** So, let's talk a bit about your association with
17 professional organizations related to pain management. Do
18 you have leadership roles in various pain management
19 organizations or have you had leadership roles?

20 **A.** I do. I've been involved in organized medicine because
21 I think it's important to try to change the field with young
22 people.

23 MS. MAINIGI: So, Matt, let's put up our second
24 slide, if we could, please.

25 BY MS. MAINIGI:

1 Q. And, again, Dr. Deer, you helped us prepare this slide;
2 is that correct?

3 A. That's correct.

4 Q. So, can you walk us through the various societies that
5 you're involved with?

6 A. I'll start. I'll try to do it in time fashion from
7 earliest to latest. So, The American Society of
8 Anesthesiologists is about a 50,000 member group that
9 actually is involved with both anesthesiology and pain and,
10 in 2004, I believe, I was asked to be the Chairman of the
11 Pain Division. I was the first private practitioner, I
12 believe, to ever hold that. It's always been academicians.
13 And I held that position for four years, developing policy
14 for anesthesiologists to treat both pain and anesthesia for
15 acute pain, like epidurals and things.

16 Then, I was on the board of American Society of
17 Interventional Pain, which is a group that looks at access
18 to care and advancement of interventional techniques.

19 And then I -- during that same time period, I was
20 President of the West Virginia Society of Interventional
21 Pain Physicians for, I think, about 15 years. Eventually,
22 the younger guys retired me and made me President Emeritus.
23 So, that's a much easier job than being President. So, I
24 have to say, I like that.

25 I was President of the International Neuromodulation

1 Society, which is -- where I've really spent a lot of my
2 time in my career. It's the advancement of innovation with
3 scientists and physicians of devices, including things like
4 brain stimulators for Parkinson's disease, spinal
5 stimulators for pain. And we also have the main goal of
6 improving access to third world countries with that. So,
7 trying to get companies to make less expensive devices so
8 that people can get access in places like India and, you
9 know, Sri Lanka and other places like that.

10 And then, lastly, and I'm sorry. I don't want to be
11 too long, but the American Society of Pain and
12 Neurosciences, I'm the Chairman, which is sort of like a
13 lifetime title. I created that society four years -- three
14 years ago. I think we have about 4,000 members now. And we
15 created it for really three reasons.

16 One is to mentor young people because a lot of these
17 other societies are great, but you have to really be around
18 a long, long time and be old to get yourself up to do
19 anything. So, we wanted young people to have a chance to
20 really play leadership roles in research and development.

21 Two is we wanted to increase research. For example, we
22 have a biomarker study paper going now. A biomarker is a
23 signal, either in blood, or urine, or genes, and we're doing
24 a lot of work on the urine right now for biomarkers that may
25 predict will you respond to a procedure. If you have a

1 procedure done and your biomarker says you're -- you have
2 bad biomarkers, for example, we my find that that's not the
3 right procedure anymore. So, we think we can advance that
4 and save a lot of money for society because we can predict
5 the outcome.

6 And then, lastly, and thirdly, we really have a
7 commitment to diversity. A lot of women have had trouble
8 getting advancement in our field. It's been a man-based
9 field, for the most part. So, we have a diversity division
10 led by my friend, Erica Peterson, a neurosurgeon in
11 Arkansas, and she's really done a great job with that. So
12 that's --

13 So, it's really -- I think we're the -- we may be the
14 biggest pain society in America now, but we're based on
15 research and procedures.

16 **Q.** Thank you, Dr. Deer.

17 Let's shift over and let's come back to West Virginia.
18 Have you been appointed to any task forces or committees
19 here in West Virginia?

20 **A.** Yes, I have.

21 MS. MAINIGI: Matt, could we put up the next
22 slide, please?

23 BY MS. MAINIGI:

24 **Q.** And, again, I think this is reflective of some of your
25 experience. Let's start with the top one, the West Virginia

1 Controlled Substance Monitoring Program, CSMP Committee.

2 Tell us about that committee.

3 **A.** So, that committee came out of the -- I believe came
4 out of the 2012 legislation that established pain clinics
5 and also established the need for doctors to review
6 prescribing history on the Board of Pharmacy record. They
7 created a committee.

8 Mike Goff, I believe, was the chairman of that
9 committee, a former police officer who now runs the Board of
10 Pharmacy, very -- a very wonderful guy. And he got a group
11 of physicians who did things like end of life care, pain
12 management.

13 We had dentists because dentists were prescribing a lot
14 of opioids post-surgery for a tooth. Like they'd give you
15 90 pills for a tooth pull and things like that. So, we got
16 all these people together and we were looking at death and
17 over-prescribing.

18 So, if someone prescribed a lot of medication and had
19 no deaths, we had the Medical Examiner that was also
20 involved. Then that was one thing. But if you had two
21 things going on, a death that we can identify to your
22 practice, you got a letter from our committee that you had
23 had a death related to your prescribing. Doesn't mean you
24 did anything wrong necessarily, but we wanted you to look at
25 your prescribing.

1 It also created a way to monitor doctor shopping. So,
2 if we had five physicians giving the same patient pills, it
3 would -- the computer system would pick that up. The
4 committee would look at it and we would say that's a real
5 red flag and we would send all of those five doctors a
6 letter that your patient has received controlled substances
7 from at least, you know, two other doctors, or whoever it
8 may be. They should have been seeing it themselves by
9 checking the computer, but most of them weren't in 2012.

10 **Q.** And we'll go over the 2012 legislation that addressed
11 opioids a little bit later, but can you tell us what the
12 CSMP is briefly? What did that do?

13 **A.** It monitors the prescribing physicians in West Virginia
14 and looks for abnormal behavior patterns. And then it looks
15 at what the specialty is. For example, if you're a family
16 doctor and you're prescribing more medicine than the
17 Chairman of Pain at WVU, although most academic people don't
18 prescribe much. Their residents and fellows prescribe for
19 them, but that's a warning sign for us. We would look at
20 that.

21 And then, it ties that together with the death data
22 from the Medical Examiner. So, that was the purpose of
23 that, the committee to look at that behavior, and then we
24 meet every few months and Mr. Goff would go over the data
25 with us and we would look at that very carefully and make

1 our recommendations to the State of what they should do.

2 **Q.** Now, the CSMP data that you all looked at, was that
3 data available to the general public?

4 **A.** I don't think so. No. I think it was to that -- the
5 Board of Pharmacy, I believe, controlled that data.

6 **Q.** Now, let's turn to the next piece here, Dr. Deer, the
7 West Virginia Safe and Effective Management of Pain, better
8 known as SEMP, guidelines that you participated in, in 2016.
9 Tell us about that.

10 **A.** So, those guidelines, and we'll talk later about the
11 CDC, Centers for Disease Control, they -- see, there's three
12 things that really helped my practice a lot. One was the
13 CDC guidelines. And we'll talk about that in more detail,
14 but the CDC said how you should prescribe medicine, which we
15 had needed for a long time.

16 And then, the CDC gave a grant to WVU and WVU was asked
17 to create guidelines for West Virginia specifically because
18 we had had our issues in Appalachia. And so, WVU reached
19 out and Mark Garo -- I can't pronounce his name but --
20 Garofoli reached out and they asked me to become the
21 Chairman of that Guideline Committee.

22 I requested doctor Rick Vaglianti be Vice-Chairman.
23 He's Director of Pain at WVU. And then we got a group of
24 physicians, pharmacists, law enforcement, regulatory bodies
25 and insurance companies to be on this panel.

1 And we looked at, you know, the national guidelines,
2 not just for CDC, but other guidelines, and tried to make a
3 playbook for doctors in West Virginia of how to do things
4 other than opioids to begin with because once you put
5 someone on a lot of opioids and send them to see someone
6 like me, I'm stuck with that opioid issue until I can find
7 other solutions. So, we prefer you do other things first
8 and that's what this is all about. And it gives you
9 different guidelines based on what's wrong with your patient
10 and it became pretty heavily adopted in West Virginia.

11 **Q.** So, the SEMP guidelines essentially gave prescribers
12 direction on how to deal with opioids?

13 **A.** The CDC, when that came out, the family doctors --
14 because that was primarily made for family physicians to
15 treat pain. So, they didn't really know what to do. This
16 gave them some guidance on what else they could do because
17 many of them had only given prescriptions their whole career
18 for opioids. They had never done anything else. So, this
19 gave them a play book and the State Medical Association
20 endorsed those guidelines and then, you know, gave them to
21 the Boards of Medicine for both allopathic and osteopathic
22 physicians, Board of Pharmacy. So, those were widely
23 disseminated to the doctors in West Virginia, and the nurse
24 practitioners and PAs, so they would have some guidance on
25 what to do when you see that chronic pain patient before you

1 start giving them a bunch of medicine.

2 Q. Thank you, Dr. Deer.

3 MS. MAINIGI: Your Honor, may we approach with
4 some exhibits?

5 THE COURT: Yes.

6 MS. MAINIGI: And what we've done, Your Honor, is
7 just for ease, we've put all of the exhibits into a binder
8 for everybody and we can -- we can just scroll through them.

9 THE WITNESS: Is my speed of speech okay?

10 THE COURT: I'm sorry?

11 THE WITNESS: Am I speaking at a good --

12 THE COURT: That would be up to the court reporter
13 here. She'll tell us if it's needed.

14 THE WITNESS: I get carried away sometimes.

15 THE COURT: I can hear you just fine.

16 THE WITNESS: Okay. Okay. Let me know if I talk
17 too fast.

18 COURT REPORTER: It's pretty rapid, if you could
19 --

20 THE WITNESS: A little bit more?

21 COURT REPORTER: Yes. I appreciate --

22 THE WITNESS: Just anytime I get too fast, let me
23 know. I'm sorry about that.

24 COURT REPORTER: Thank you. Thank you. I'd
25 appreciate that.

1 BY MS. MAINIGI:

2 Q. So, Dr. Deer, I'm going to ask you to take a look at
3 the first exhibit I hope that's in your binder, which is
4 DEF-WV-03036.

5 MS. MAINIGI: Now, this document, Your Honor, was
6 admitted during Dr. Gupta's testimony. So, that's an
7 admitted document.

8 BY MS. MAINIGI:

9 Q. Is that the SEMP Guidelines, Dr. Deer?

10 A. Yes, it is.

11 Q. Now, if you turn to Page 4 of the document, Page 4
12 identifies the individuals who worked on the SEMP guidelines
13 along with you?

14 A. That's correct.

15 Q. Now, I think you might have mentioned this, but just
16 for clarity, were there state government officials and
17 employees involved in the SEMP guidelines?

18 A. Yes, there were.

19 Q. And who were some of those folks?

20 A. So, if you look through the list there, Dr. Gupta was
21 involved. He was a West Virginia DHHR person at the time.
22 At that time, we also had the Rational Drug Program Therapy
23 Director. We had the WVU School of Pharmacy and Medicine
24 Director. We had the W -- the University Head of the PharmD
25 program. There was also involvement of Mr. Goff, who is on

1 the Board of Pharmacy. So, those are some of the folks that
2 were involved in the area of the state government.

3 **Q.** These -- so, these 2016 SEMP guidelines in West
4 Virginia, has the -- to your knowledge, has the West
5 Virginia State Medical Association endorsed the guidelines?

6 **A.** The West Virginia State Medical Association has
7 endorsed the guidelines.

8 **Q.** And how about the West Virginia Pharmacists
9 Association, have they endorsed the guidelines?

10 **A.** They have.

11 **Q.** And, to your knowledge, do doctors in West Virginia
12 rely on the SEMP guidelines in their practice?

13 **A.** I certainly believe they do. I've had a lot of
14 discussions with doctors around the state and found this to
15 be helpful to them; some who didn't like it because they
16 thought it was too restrictive. So, I've heard both sides.
17 I know they actually read them.

18 **Q.** Now, let me shift over to another set of guidelines.

19 MS. MAINIGI: If we can go back to the prior
20 demonstrative, Matt, please.

21 BY MS. MAINIGI:

22 **Q.** Dr. Deer, you also did some work with the West Virginia
23 Coalition for Responsible Chronic Pain Management and was
24 that an organization created by the West Virginia
25 Legislature?

1 **A.** It was.

2 **Q.** And that was created in 2017?

3 **A.** That's correct.

4 **Q.** Who were the other members of this coalition appointed
5 by the legislature?

6 **A.** So, from memory, I'll have to do my best, but the
7 Director of Public Health Medicine at WVU chaired the
8 committee. We had several pain physicians from around the
9 state, including those who were in small practices doing
10 injections and procedures. And we also had -- it was led
11 by, again, West Virginia Public Health. So, you know, as
12 far as the actual names on there, I -- show me a list, I
13 could certainly help you with that, but I can't recall at
14 this point all the names on there.

15 **Q.** Well, we'll keep moving so we can get through your
16 background.

17 Now, in addition to the SEMP guidelines, have you
18 participated, Dr. Deer, in creating any other opioid-related
19 guidelines?

20 **A.** I have.

21 **Q.** And what were those other guidelines?

22 **A.** So, the American Society of Interventional Pain
23 Physicians, as we talked about a little bit earlier, is
24 primarily based on advancing innovation-like procedures.
25 But, also, many of the members, because they receive

1 referred patients on high dose opioids, need some guidance.
2 So, I was on a consensus group that's now had three
3 different iterations look, because the standard of care
4 changes over time, looking at proper ways to both prescribe
5 opioids, but also, to monitor opioids.

6 **Q.** And, as I understand it, ASIPP, as this organization is
7 known, issued guidelines in 2006, 2012 and 2017. Does that
8 sound right to you?

9 **A.** That's correct. And I believe, in '22, we'll have
10 another set of guidelines.

11 **Q.** And why were guidelines issued in those time periods?

12 **A.** Because over time standard of care changes and I think
13 as it changes, based on research, development and new
14 information, you have to change -- whether you're talking
15 about a surgery, or a medication, or monitoring. And if you
16 don't change with it, then you would be no longer within the
17 standard of care.

18 **Q.** We're almost done with your qualifications and
19 background.

20 MS. MAINIGI: Matt, let's put up Slide 4, please.

21 BY MS. MAINIGI:

22 **Q.** Now, Dr. Deer, have you been published in your field?

23 **A.** I have. I'm getting close, I think, to 300 articles
24 right now.

25 **Q.** And have you had roles editing journals on topics

1 relating to pain management?

2 **A.** I have. I've been on the Editorial Board of multiple
3 journals and then the Associate Editor of Neuromodulation.

4 **Q.** And have you, in fact, even published your own
5 practitioners guide, second bullet there?

6 **A.** Yeah. So, Deer's Treatment of Pain is a textbook we
7 published, I believe, in '19 that's been commonly used for
8 residents and fellows around the country and in
9 international areas. It's used also through Europe.

10 **Q.** Do you also teach?

11 **A.** I do. I'm at WVU, as far as a clinical professor,
12 which means that medical students rotate with me. I usually
13 have one or two at a time from WVU and, also, the
14 osteopathic schools, their fourth year students. I have one
15 right now that is working with me.

16 Also, I've been a visiting professor at many
17 institutions, Mayo Clinic, Cleveland Clinic, Harvard,
18 Stanford. So, I go and spend a few days with fellows in
19 other areas to talk about some of the research I've done.

20 **Q.** Now, have you ever testified before the West Virginia
21 Legislature on topics related to pain management?

22 **A.** I have. I've been invited to give my thoughts to many
23 committees within the legislature over the years.

24 **Q.** Have you ever testified as an expert in litigation
25 before, Dr. Deer?

1 **A.** I have.

2 **Q.** And have you specifically testified as an expert on
3 pain management previously?

4 **A.** Yes, I have.

5 **Q.** Do you recall about how many times courts have found
6 you qualified to testify as an expert?

7 **A.** I would estimate around 30 times. I'm not sure that
8 number is exactly correct, but somewhere in that vicinity
9 would be probably accurate.

10 **Q.** Do you have any sense of how many times it was in
11 federal court?

12 **A.** I think as an expert in federal court three times. I
13 think I was a treating physician in federal court many years
14 ago. I don't know if you could --

15 **Q.** You don't get credit for that?

16 **A.** I don't think you get proof of that, but I did testify
17 in federal court in both New York and also in Delaware on at
18 least three occasions.

19 **Q.** And have you also consulted on litigation for the U. S.
20 Attorney's Office here in Charleston?

21 **A.** Yes. I've worked with the U. S. Attorney's Office both
22 here in Charleston, but also, I think up in the Beckley
23 region and also in North Carolina.

24 **Q.** And I don't want to get into, obviously, any details of
25 cases, but did your work involve consulting on improper

1 opioid prescribing?

2 **A.** Yes. It was looking at people prescribing improperly
3 for no medical reason and fraud.

4 MS. MAINIGI: Your Honor, at this time, I would
5 like to tender Dr. Deer as an expert in pain management and
6 the standard of care for pain management.

7 THE COURT: Any objection?

8 Hearing none, the Court finds Dr. Deer to be an expert
9 in pain management and the standard of care for pain
10 management.

11 MS. MAINIGI: Thank you, Your Honor.

12 BY MS. MAINIGI:

13 **Q.** Dr. Deer, in your experience, who is it that makes the
14 decision to write a prescription for an opioid medication to
15 a patient?

16 **A.** It would be the physician or clinical practice person,
17 which may be a nurse practitioner in some instances.

18 **Q.** And, in your opinion, is it appropriate to prescribe
19 opioids for pain management in various instances?

20 **A.** In the correct patient, it can be very appropriate.

21 **Q.** Now, let's turn to the basis for your expert opinion.
22 At a high level, what is the question you were asked to look
23 at and answer in this case?

24 **A.** So, I was asked to look at the standard of care in West
25 Virginia from my arrival here in 1994 until 2021 and how it

1 changed regarding opioid prescribing and really what
2 happened in West Virginia.

3 **Q.** And were you -- you were focused specifically on West
4 Virginia across the board?

5 **A.** That's correct.

6 **Q.** Okay. And are you also familiar with what was
7 happening nationally at the same time?

8 **A.** As I testified earlier, I'm very involved in national
9 societies, so I do know the national, really, overview.
10 And, also, I know a lot of the folks nationally who were
11 giving lectures on proper opioid prescribing back in those
12 days who we may talk about later.

13 **Q.** So, how did you go about answering the question that
14 you were charged with?

15 **A.** Well, so --

16 **Q.** What did you do?

17 **A.** First of all, you know, I've been here a long time. I
18 don't feel as old as I am, but that's how life goes. So,
19 I've been here a long time. And so, I have my personal
20 experience, you know, treating well over a hundred thousand
21 patients over the years.

22 But, also, you know, I have looked at what happened
23 with, you know, policies around the state legislature, what
24 happened with societies, which we have members of societies
25 in West Virginia, what happened with the education of

1 doctors. So, I looked at all of those factors and I think
2 it really gives a good insight, in my opinion, of what
3 happened here and what's going on today.

4 **Q.** And were you able to form an opinion, Dr. Deer, with
5 reasonable degree of certainty about how the standard of
6 care for the use of opioid medications and the treatment of
7 pain changed between the early 90s through today?

8 **A.** I felt very confident that I have a very good
9 impression of how it changed from 1994 until 2021.

10 MS. MAINIGI: Matt, if we could put up the next
11 slide, please.

12 BY MS. MAINIGI:

13 **Q.** Dr. Deer, did you help us prepare this demonstrative
14 which provides an overview of where you're going with your
15 opinions?

16 **A.** I did.

17 **Q.** So, tell us at a high level, what is your opinion?

18 **A.** Well, so, at a high level, there's -- in my career
19 there's been three main phases in West Virginia. There was
20 the initial when I first got here and right before I got
21 here there was a liberalization of prescribing of opioids
22 for basically anyone who complained of pain around the
23 state. And then, that went on until around 2010.

24 **Q.** And it started about when?

25 **A.** Probably in the late 80s as legislation and articles

1 started to appear in national and international literature
2 that it was a human right to be treated for pain. So,
3 probably late 80s. And then, in the early 90s, we saw more
4 prescribing. And then, around 1996, it changed
5 dramatically.

6 **Q.** And why did it change dramatically in '96?

7 **A.** Because new drugs came along that were really said to
8 be less addictive and, certainly, most physicians believed
9 that to be true.

10 **Q.** And are you referring specifically to Oxy, which is
11 manufactured by Purdue?

12 **A.** The primary drug was OxyContin. I mean, MS Contin and
13 thera-gesic patches were also in that group, but OxyContin
14 was the primary drug that was going to be the wonder drug,
15 if you will. We all believed that to be probably the case
16 based on the marketing and research at the company who
17 developed that drug.

18 **Q.** Now, so, in this first phase, which you said went until
19 about 2010; is that right?

20 **A.** I can -- again, that's a number I can live with.
21 Certainly, some of those lines are blurry of what exact
22 years that may be.

23 **Q.** So, did you see then the standard of care evolve
24 towards prescribing more opioids?

25 **A.** Oh, absolutely. You know, as a referral-only practice,

1 you know, we would get -- you know, if you get a patient
2 sent to you from Oceana on ten pills a day and you take over
3 their care, you know, that's 300 pills a month. That's 360
4 pills a year for one patient. You can't just take them off
5 that day, right? You have to make adjustments and you have
6 to try other things. So, we would get those patients, you
7 know, and, certainly, we would have to find solutions for
8 them because, obviously, that's -- I never felt that was
9 going to be an appropriate long-term dose for the patients.
10 So, we saw that from -- really, as the 90s progressed, we
11 saw more and more of that, all the way -- and we'd get
12 people off, 80-85 percent of people either off or reduced by
13 half. But then, new patients would come in. So, the funnel
14 kept filling up. So, I saw it firsthand every day of my
15 practice.

16 **Q.** So, let me pause on one thing. You mentioned -- we
17 spoke just a moment ago about Purdue. Did you personally
18 have any professional interactions with Purdue during this
19 time period, this first phase?

20 **A.** I did. So, Purdue Frederick was a company that
21 presented research that OxyContin was less addictive and
22 long-term solution for chronic people who needed opioids.
23 They also sponsored several county societies. So, for CAMC,
24 for Thomas, for St. Francis.

25 I would go out to Roane County, for example, or Raleigh

1 County, or Huntington to give ground rounds and they would
2 have a sponsor for the event. And so, they would both give
3 the honorary to the speaker, which was \$500 or a \$1,000.00.
4 They would also sponsor the event itself. And so, I did
5 work in that capacity and --

6 **Q.** Did there come a time when you decided to stop doing
7 work for Purdue?

8 **A.** Well, so, you know, I -- from 1996, when they came out
9 until probably the early part of 2000, I really felt that
10 the teaching around the country that long-term opioids were
11 better than short-term was correct until I started seeing
12 more and more of what was going on with the drug OxyContin.

13 And when I gave a lecture -- just to be clear, when I
14 gave a lecture they were sponsoring a program on, I always
15 talk about the same thing. I talk about procedures as a way
16 to spare people from opioids when possible. So, I would
17 talk about that and I wouldn't use their slides. And so,
18 that was an issue with them a bit.

19 **Q.** Did something happen in the early '00s that caused you
20 to stop even participating in anything they sponsored?

21 **A.** It did. Two things happened. I actually heard some of
22 their speakers talk about you could give people with alcohol
23 addiction their drug and it wouldn't be a problem. I felt
24 that was totally crazy. Every -- every bit of information
25 says that's wrong.

1 And then, Dr. Haddox, who was their Medical Director,
2 talked a lot about, you know, that no one was really
3 addicted, they were undertreated, you give them more and
4 more. And I heard him -- we were speaking together at
5 Embassy Suites at a meeting put on by the State Medical
6 Association. I was speaking on procedures, he was speaking
7 on opioids, and I really felt that was bad information to
8 give physicians. So, we had a real break in our thought
9 processes.

10 **Q.** Now, after you had this experience with Purdue, did you
11 stop prescribing opioids?

12 **A.** No. I think opioids -- again, it's a complicated
13 issue. When we get referrals on a patient that's been on an
14 opioid for three years and they say it's helping them and
15 their urine screen is good and they've been compliant with
16 their family doctor, you can't easily just take them off
17 their opioid. You have to find a solution to help them.

18 Most people that get to see us want to get off of
19 opioids. That's why they often request from the family
20 physician, I want to go see Dr. Kim or Dr. Deer, one of my
21 colleagues. And so, we then come up with a strategy, a
22 plan.

23 Many of those people, for example, have never been to
24 physical therapy. Something that simple. We have a
25 physical therapy department. Many of those people had a,

1 you know, a joint problem that we can easily burn the joint
2 and help them, but they've never been offered that. So, a
3 lot of times, it was just the family physician didn't know
4 what options existed. And so -- so, we didn't quit
5 prescribing opioids in general and, in fact, we didn't quit
6 prescribing Oxycodone in patients who were on it already,
7 but we did try to find other solutions and I no longer
8 believed the comment that it wasn't addictive because I
9 started seeing some people have an addiction in the
10 community.

11 **Q.** Now, let's shift over to your second phase. So, you've
12 got the first phase. And describe to me what you saw
13 happening in this 2010 to 2015 time period with the second
14 phase.

15 **A.** Well, so, you know, we started seeing more discussion
16 about the problem, you know, and I think it became -- people
17 started pushing back a bit. We had -- and we'll talk in
18 more detail, but we had everyone saying you have to up the
19 dose. You have to treat the patient with opioids. You have
20 to look at the fifth vital sign and make sure they are
21 treated properly.

22 And then, in 2010 or so, we starting seeing people like
23 myself pushing back and saying I'm not sure that's right.
24 We need to look at it carefully.

25 And, in 2012, the West Virginia Legislature asked for

1 advice from myself and others and they created the West
2 Virginia act that made pain clinics be certified. And what
3 I mean by that is, if someone gave more than 51 percent of
4 their patients a controlled substance, they fell under that
5 legislation even if they were a family doctor because, at
6 that time, you could be a family physician calling yourself
7 a pain clinic giving people opioids all day long, right?
8 That was appropriate under the rules before 2012 in West
9 Virginia.

10 In 2012, that legislation said you have to meet certain
11 criteria to be treating pain chronically. And I think that
12 was a big step forward in '12. It wasn't enough probably to
13 change the standard of care, we'll talk more about that
14 later, but it helped.

15 **Q.** Let's talk about the third phase then, 2015 through --
16 through the present. Describe for us what was happening
17 particularly in West Virginia during that phase.

18 **A.** So, in '15 to '21, I think, again, we've seen a really
19 good change in West Virginia, I think, and it goes back to
20 several factors. One is the CDC came out with guidelines
21 and while it's a national thing, local physicians in West
22 Virginia -- and, again, they were -- they were written
23 originally for primary care and family practice.

24 People who had given people high dose opioids for years
25 read the CDC guidelines. 15 morphine equivalents should be

1 what the goal is, or less. 98 at the most unless someone is
2 end of life. And that really made people change their
3 prescribing some, not all, but it helped.

4 Then the SEMP guidelines came out in '16 and we
5 published those. That helped because then they had a way to
6 enforce or adjudicate the CDC guidelines in their practice.

7 And then, thirdly, and I think probably most
8 importantly for me because if you watch my prescribing
9 taking people over in this '10, '11, which was up here
10 because I got those people coming to me that way versus '18
11 and now through '21.

12 We saw the 2018 legislation in West Virginia about
13 limiting prescribing, which was the best thing that's
14 happened to our state, in my opinion, as far as this issue
15 goes, really limit how much family physicians gave patients
16 before they sent them to see me.

17 So, now, most patients sent to see us, unless they're
18 cancer patients on minimal or no opioid. So, that
19 conservatism phase, I think, has been very -- in my opinion,
20 very good for the people in West Virginia.

21 **Q.** So, in addition to your own practice, did you see a
22 change in this later third time period in prescribing trends
23 in West Virginia?

24 **A.** Oh, absolutely. I think if you look at the West
25 Virginia data from the last few years overall, hydrocodone

1 and oxycodone both are way down as prescribed for patients.
2 Also, many family physicians from all over the state,
3 really, that '18 law scared them a bit because they had been
4 prescribing in ways that were not anywhere remotely familiar
5 to the '18 law. So, I had phone calls from probably, you
6 know, a third of the family physicians in West Virginia
7 asking me what they should do. And so, that was good
8 because, in the past, I didn't get those phone calls. So, I
9 think that was a good thing.

10 **Q.** And so, it sounds like you've also changed or adjusted
11 your own opioid prescribing in the last several years?

12 **A.** Oh. Absolutely. So, you know, to give you an example,
13 in 2005, when we received a patient on high dose OxyContin
14 and, again, they had no signs of addiction, their drug -- we
15 screen everybody with a drug screen from the day we meet
16 them. The drug screen was good. The Board of Pharmacy was
17 good, but they were on this high dose. We would have to
18 figure out how to get them off that drug and do other
19 things, right, make -- sometimes, it took a long time
20 because the patient had really bad problems. Sometimes, it
21 took a long time because of insurance approval of
22 procedures.

23 For example, Medicaid would not approve procedures, but
24 they would approve the drug. So, it really -- we take
25 Medicaid or practices that do take Medicaid. So, we saw all

1 that going on and sometimes it would take us three or
2 four years to get someone down below the 15 morphine
3 equivalence or off the medication.

4 And then, 2020, if I'd get 100 patients in a month,
5 maybe two or three will be on opioids.

6 So, I mean, I can't tell you the difference. It's
7 amazing. You can see it in my numbers, for example,
8 because, again, remember, we take only referred patients.
9 So, we only see you if your doctor has already treated you
10 for at least three to six months.

11 So, I think it's been striking to me what those three
12 things we just talked about, the CDC, SEMP and the state
13 legislation did to improve that.

14 **Q.** So, let's come back for a moment and define standard of
15 care. Can you tell the Court what you mean when you use
16 that phrase?

17 **A.** So, standard of care means what a reasonable doctor
18 would do within their field of medicine in a situation and
19 that's the standard of care.

20 **Q.** And are standards of care typically written down or
21 formalized?

22 **A.** Some are written down. For example, guidelines that we
23 write for devices, if it says give antibiotics before
24 surgery, if we don't do that and the person gets an
25 infection, you're going to probably be in trouble. So,

1 that's a written standard of care.

2 Some aren't written; they're understood. For example,
3 you know, I just read a book on the Spanish Flu and Johns
4 Hopkins in those days, they would bleed you for Spanish Flu
5 and that was standard of care. Didn't work very well in
6 1918. But today, if you did that, you would lose your
7 license. So, I mean, standard of changes based on, you
8 know, common knowledge. Everyone decided that was a bad
9 idea. So, that's not written down, but it doesn't need to
10 be.

11 **Q.** So, the standard of care is not static? It can be
12 dynamic?

13 **A.** It's usually dynamic in most things. There are certain
14 rules that I think that always stay the same, but in many
15 areas of care, it changes based on new evidence or research
16 and that's why research is so important.

17 **Q.** And are prescribers expected to prescribe medications
18 consistent with whatever the then existing standard of care
19 is?

20 **A.** I don't know about the word expected, but I think
21 physicians do follow the standard of care. So, if you're
22 told you're undertreating people and, again, back in that
23 first phase, I was often called to M&M conferences at
24 hospitals to give my opinion was the doctor undertreating
25 someone because a complaint would come in.

1 So, if you're told that you're undertreating people,
2 you get more likely to treat people with opioids. If you're
3 told you're overtreating people, you tend to back off. So,
4 I think they do change with -- I think doctors do change
5 their prescribing habits based on the standard of care.

6 **Q.** And to your -- it sounds like this is what you're
7 alluding to. To your experience, can there be consequences
8 for prescribers if they don't follow the existing standard
9 of care?

10 **A.** Sometimes. I mean, there are people that I see
11 patients from who I think did a terrible job with the
12 standard of care, but nothing happened to them because the
13 patient had no harm. But other people may lose their
14 license.

15 And you asked me about the federal prosecutors I've
16 worked with in the past and people have lost licenses and
17 gone to jail for prescribing without a medical reason or
18 they can lose their Board of Medicine license or they can
19 get sued in civil court for malpractice.

20 **Q.** So, Dr. Deer, who has access to the information needed
21 to determine whether a prescriber is prescribing consistent
22 with the standard of care?

23 **A.** Well, I would -- I will give you my best answer and it
24 may be not totally correct. I think the Board of Pharmacy,
25 the DEA and, eventually, the Board of Medicine if it's given

1 to them.

2 **Q.** And in your experience, Dr. Deer, do wholesale
3 distributors have access to information that would allow
4 them to determine whether a particular doctor is prescribing
5 within the standard of care?

6 **A.** Not in my --

7 MR. FITZSIMMONS: Objection.

8 THE WITNESS: I'm sorry, sir.

9 MR. FITZSIMMONS: I need to object. I believe
10 it's outside the scope of the qualification for the standard
11 of care. We're now bringing in acts of the distributorship
12 which, according to the report, is limited not to -- does
13 not include the distributorship conduct whatsoever.

14 THE COURT: Well, overruled. I'm going to let him
15 answer, if he knows, from his own personal knowledge.

16 THE WITNESS: I don't have any knowledge of any
17 distributor involvement in that based on my personal
18 experience.

19 BY MS. MAINIGI:

20 **Q.** So, I want to focus back on the standard of care for
21 pain management.

22 THE COURT: I think I should sustain the objection
23 in view of his last answer, Ms. Mainigi. You go ahead.

24 MS. MAINIGI: Thank you, Your Honor.

25 BY MS. MAINIGI:

1 **Q.** When did you see the standard of care begin to change?

2 **A.** That's a complicated question. Could you rephrase
3 that? I'm not sure I understand.

4 **Q.** Yeah. No, that is -- that is not a good question.

5 So, for example, when you were in medical school, was
6 it the standard for physicians to routinely prescribe opioid
7 medications for chronic pain?

8 **A.** So, when I was at WVU, you know, we didn't have any
9 lectures on pain at all and that was pretty common. Now,
10 I'm working with some people at Hopkins to make a good
11 curriculum for medical schools. And the only thing I saw
12 with opioids there was a doctor named Dr. Moss (phonetic),
13 who was Head of Palliative Care. And that was really all I
14 saw opioid-wise when I was a medical student. I would see
15 people after surgery get opioids, usually Tylox or Percocet.
16 And so, that was about it in med school.

17 **Q.** And so, did you come by the mid-90s to know of a
18 concept called pain as the fifth vital sign?

19 **A.** So, when I was leaving UVA coming here, I was starting
20 to see at UVA people on a lot of pills a day, short-acting
21 pills. And so, I was starting to see a change a little bit
22 in the early '90s, but it wasn't to the point it got to much
23 later.

24 So, when I came to West Virginia, I started hearing
25 about the fifth vital sign as I went to society meetings and

1 Joint Commission and things of that nature. So, that became
2 a term that was really propagated around the United States.

3 You know, you have your blood pressure. You have a
4 pulse. You have your respiratory rate. You have your
5 temperature. That's what most -- you know, I have a
6 daughter who is a nurse. That's what most nurses would
7 check in the hospital.

8 And then, it was added to the Veterans Administration,
9 which I know there's one down in Huntington, as well as the
10 Joint Commission accredited hospitals, a fifth vital sign,
11 which was pain assessment and treatment.

12 **Q.** And so, pain as the fifth vital sign, that meant that
13 that was something like blood pressure that actually got
14 asked about at the hospital or tested?

15 **A.** Once that became accepted as an important factor, it
16 was required. You know, when you asked me earlier about
17 CAMC, one of the reasons I became Medical Director of CAMC
18 of Pain, they had to meet the Joint Commission requirements
19 as pain for the fifth vital sign. It meant that every
20 patient that walks in the hospital, inpatient or outpatient,
21 or to the VA, had to ask the pain level and follow that
22 throughout the care and then make adjustments to the pain
23 and get the pain below a five out of ten.

24 **Q.** And so, were there several organizations that promoted
25 pain as the fifth vital sign?

1 **A.** There were several. I think the biggest was American
2 Pain Society, which was a society dealing with mostly
3 non-interventional pain.

4 **Q.** And have you ever been a member of the American Pain
5 Society?

6 **A.** I was. I joined that society, like many other
7 societies, early on, never played any leadership role there
8 in any fashion because they were more non-interventional,
9 but they had a journal called Pain, which was the highest
10 rated journal in our field for many years, and we published
11 an article on stimulation of the spine there in 2015 that's
12 a landmark article.

13 **Q.** And, at the time, did you view the American Pain
14 Society as a respected organization?

15 **A.** They had some of the more experienced doctors in the
16 field, mostly non-interventional, but some of the more
17 well-published doctors. So, yes, they were well respected
18 back in those days.

19 MS. MAINIGI: Your Honor, I'd like to put up on
20 the screen DEF-WV-02395.

21 Matt, if you could put that up, please.

22 BY MS. MAINIGI:

23 **Q.** Do you recognize, Dr. Deer, this document from the
24 American Pain Society?

25 **A.** I do. It was widely seen around our field.

1 Q. Okay. And can you describe it? What is it?

2 A. So, this is a document by the society, American Pain
3 Society, from 1995, right after I got to West Virginia and
4 the year after. And then, it's a statement from the --
5 presidential address from Dr. James Campbell, who I know
6 well from Johns Hopkins. He was from the Department of
7 Neurosurgery there and he was giving the keynote address and
8 he called for this change and then their board agreed with
9 him and made a push to make that important.

10 Q. So, James Campbell was the Head of the American Pain
11 Society at the time?

12 A. Yes, he was.

13 Q. And he was -- he practiced at Johns Hopkins?

14 A. He still does. I had a call with him about an
15 experiment in the spinal fluid a few months ago, but he
16 still -- but he doesn't see patients any longer. He does
17 research only now, I think.

18 Q. So, if you could --

19 MS. MAINIGI: Matt, if we could highlight the
20 statement from Dr. Campbell at the top.

21 BY MS. MAINIGI:

22 Q. If you could read that out loud, please?

23 A. I'll try my best. That's a long way from me.

24 Q. And I'm sorry, Dr. Deer. You have a binder in front of
25 you.

1 **A.** Oh, okay. I think I can do it.

2 **Q.** Okay.

3 **A.** It's not on, but I'll try my best to read that from
4 here. I feel like I'm at the Department of Motor Vehicles.

5 **Q.** You're at the opthamologist.

6 **A.** Vital signs are taken seriously. If pain were assessed
7 with the same zeal as other vital signs are, it would have a
8 much better chance of being treated properly. We need to
9 train doctors and nurses to treat pain as a vital sign.
10 Quality care means that pain is measured and treated. Dr.
11 Campbell.

12 **Q.** You did a good job with that. Thank you.

13 **A.** Thanks. I can't go any smaller than that from this
14 distance, please.

15 **Q.** Now, is it not up on your screen, Dr. Deer?

16 **A.** No. There's nothing up on my screen.

17 **Q.** Oh, okay.

18 **A.** It's dark.

19 **Q.** The binder in front of you -- well, next time, we'll
20 turn to the binder.

21 **A.** Oh, thank you.

22 **Q.** So, this document was in '95 and then OxyContin came
23 out in 1996; is that right?

24 **A.** Not exactly. OxyContin, I believe, was actually
25 approved in '95. I think '96 was when Purdue Frederick

1 started to market OxyContin as a product, but I think it was
2 approved in '95, if I remember correctly.

3 **Q.** Now, in your opinion, did these messages from Dr.
4 Campbell and the American Pain Society affect the medical
5 community?

6 **A.** Oh, they were -- they were hugely impactful [sic] and
7 people made changes immediately to their practice because of
8 this fifth vital sign.

9 **Q.** How do you know that?

10 **A.** I lived through it. Everybody admitted to the hospital
11 had to be treated -- to go home like, for example, if you
12 had your knee replaced, at that time, Dave Santrock was
13 doing a lot of knee replacements at my hospital, one of my
14 dear friends. And so, he would replace your knee and before
15 you'd go home Day 2 or 3, but after this came about, you
16 couldn't go home unless your pain was down to a 4.

17 So, most doctors, I mean, there are people like me. I
18 can go do a nerve block. I can do a femoral nerve block to
19 help your knee pain and you might go home.

20 But most doctors don't do that type of procedure. So,
21 they would give you, you know, pills because they had to get
22 you below 4. So, when people left the hospital, they had a
23 month's pills and they went back to their family doctor.
24 And then, many times, they stayed on their pills because
25 they've got chronic knee pain even though they had the

1 replacement. So, that really changed greatly anybody that
2 went to the hospital for any reason, including outpatient
3 treatment, how they were treating them.

4 MS. MAINIGI: Your Honor, I would like to move to
5 admit 02395 into evidence.

6 THE COURT: Any objection?

7 MR. FITZSIMMONS: No objection.

8 THE COURT: It's admitted.

9 By MS. MAINIGI:

10 Q. I'm going to ask you -- and let's let you turn in your
11 binder, Dr. Deer --

12 A. I have the screen now.

13 Q. -- if that's helpful. Oh, you have the screen now?
14 Okay.

15 MS. MAINIGI: Matt, if you could put on the screen
16 DEF-WV-03074, it should be the next document in the binder.

17 BY MS. MAINIGI:

18 Q. Now, this is a document from the VA entitled Pain as
19 the Fifth Vital Sign Tool Kit. Are you familiar with this
20 document?

21 A. Yes, I am.

22 Q. And what's the date on the document, just so we can
23 place it?

24 A. October 2000.

25 Q. Now, let's turn to Page 13, if you could, of the

1 document, and there's a section there, Section 4, called The
2 Pain Screening Process. Could you read that section,
3 please?

4 **A.** Be happy to. Pain as the fifth vital sign is a
5 strategy for promoting increased attention to unrecognized
6 and undertreated pain among patients receiving care in the
7 Veterans Hospital Administration healthcare system. The
8 strategy calls for a routine screening, where patients are
9 asked whether they are experiencing pain and are then asked
10 to rate the intensity of their pain using the 0 to 10
11 numeric rating scale on which 0 equals no pain while 10
12 represents the worst possible pain. The number reported by
13 each patient is the pain score and should be documented in
14 the medical record. The presence of pain at any level
15 serves as a cue to the provider to conduct additional
16 assessment and to initiate interventions designed to promote
17 pain relief, as clinically indicated.

18 **Q.** So, is this document from the VA an example of an
19 organization promoting the under -- promoting the fact that
20 pain is undertreated and should be dealt with?

21 **A.** That's correct.

22 MS. MAINIGI: Your Honor, at this time, I would
23 like to move for the admission of 03074 into evidence.

24 THE COURT: Any objection?

25 MR. FITZSIMMONS: No objection, Your Honor.

1 THE COURT: It's admitted.

2 By MS. MAINIGI:

3 Q. Now, that was the VA. Are you aware if during this
4 time period, Dr. Deer, hospitals also began to adopt
5 policies to address the undertreatment of pain?

6 A. So, most hospitals that anyone in this room will go to,
7 hopefully, are accredited because that's important that they
8 meet standards. Joint Commission adopted the fifth vital
9 sign as one of those standards of approval of your hospital
10 facility or outpatient surgery center.

11 Q. And let me ask you to turn -- well, you can look at the
12 screen, if you'd prefer, but it is -- the document is
13 WV-2693 in the binder. Should be the next tab. It's the
14 Joint Commission pain standards which have already been
15 admitted for a limited purpose under Dr. Gilligan. Are
16 these, in fact, the Joint Commission pain standards?

17 A. Those are that document, yes, ma'am.

18 Q. And those are from 2001?

19 A. Correct.

20 Q. And do you have an opinion, Dr. Deer, as to what impact
21 this guidance, along with the APS guidance and the VA
22 guidance, had on the standard of care for prescribing
23 opioids during this time period?

24 A. I feel it greatly shifted, in my experience, the
25 standard of care towards more opioid prescribing for anyone

1 admitted to any hospital.

2 **Q.** Now, this guidance doesn't expressly tell doctors to
3 prescribe more opioids, does it?

4 **A.** It does not.

5 **Q.** So, why did it change the standard of care?

6 **A.** Because, you know, there's an old saying if you have a
7 hammer that looks like a nail in medicine where you do the
8 same thing for everyone. So, if you went to see in a
9 hospital that had someone who could do a shoulder block
10 after shoulder surgery, you may get that. It may help your
11 shoulder pain to get you home. We do a lot of those today
12 in 2021.

13 But if you didn't have someone to do a block if you had
14 a shoulder replacement or a rotator cuff repair, that's
15 quite painful. So, to get you out of the hospital, you
16 know, originally, it said pain below 5, but as you saw in
17 that thing I just read, it said any pain at all. If you
18 complain of pain, many physicians who are good physicians,
19 who didn't -- wasn't trying to cause harm, gave the person
20 opioids in the hospital by IV and then shifted to pills to
21 let them go home because, otherwise, they couldn't meet the
22 standard -- the Joint Commission standards.

23 **Q.** And this change in the standard of care during this
24 time period, was that consistent with the practice you saw
25 at hospitals in West Virginia?

1 **A.** Oh, absolutely.

2 **Q.** And, to your knowledge, did this pain as the fifth
3 vital sign concept affect prescribing by doctors outside of
4 the VA and outside of hospitals, as well?

5 **A.** I think it did because, again, when those patients went
6 back to their home, then they often had been taking opioids
7 successfully, giving them pain relief. The family doctor
8 would often keep them on that medication.

9 **Q.** Now, were prescribers at the time who prescribed more
10 opioids in accordance with that changing standard of care,
11 were they, in your opinion, acting reasonably in light of
12 the information available to them at the time?

13 **A.** Based on their knowledge base and their options, they
14 were, based on the information.

15 **Q.** Now, are you aware of whether wholesale distributors
16 had any involvement in any of these documents?

17 MR. FITZSIMMONS: Judge, I'm going to object. I
18 thought we already established that it's (unintelligible) --

19 COURT REPORTER: I'm sorry, sir. I'm having
20 trouble hearing you. Is your mic on?

21 MR. FITZSIMMONS: I'm sorry. Is my mic on?

22 COURT REPORTER: I don't think so.

23 MR. FITZSIMMONS: It's not. I'm sorry. I
24 apologize.

25 I thought we already objected once as to the area of a

1 distributorship's action and this is -- I believe Your Honor
2 sustained that objection and this question is specific,
3 trying to elicit now distributorship conduct by this
4 witness, who has already testified he knows nothing about
5 that.

6 THE COURT: Well, I'm going to let him answer the
7 question if he can. The reason I sustained the last
8 objection was that he said he didn't -- he didn't know.

9 MR. FITZSIMMONS: That's correct, Judge. That's
10 why I'm objecting again.

11 THE COURT: That's --

12 MR. FITZSIMMONS: And unless he changes his
13 testimony --

14 THE COURT: I'll reserve my ruling and let you
15 question him a little further, Ms. Mainigi.

16 MS. MAINIGI: Thank you, Your Honor.

17 BY MS. MAINIGI:

18 **Q.** Do you remember the question, Dr. Deer?

19 **A.** Please repeat it.

20 **Q.** Absolutely. Do you have -- are you aware of any
21 distributor involvement in any of these documents that we've
22 been talking about, the Joint Commission, the VA tool kit?

23 **A.** I have no knowledge of any distributor roles or
24 actions.

25 THE COURT: I'll overrule the objection, Mr.

1 Fitzsimmons.

2 BY MS. MAINIGI:

3 Q. Now, at the same time --

4 THE COURT: The question went to what he
5 personally knew and he said he didn't have any knowledge and
6 I think the answer was appropriately admitted.

7 MR. FITZSIMMONS: Thank you, Your Honor.

8 BY MS. MAINIGI:

9 Q. Dr. Deer, around the same time that the Joint
10 Commission issued its standards in 2001, did the DEA issue a
11 statement related to the treatment of pain?

12 A. They did.

13 Q. Okay.

14 MS. MAINIGI: I'm going to ask, Matt, that we put
15 on the screen MCWV-01522, which is already admitted for
16 limited purpose under Dr. Gilligan.

17 BY MS. MAINIGI:

18 Q. And, Dr. Deer, is this a statement that you were
19 referring to?

20 A. It is.

21 Q. And this statement from the DEA, as well as 21 health
22 organizations in 2001, is this statement consistent with the
23 standard of care that you just testified about?

24 A. That is one of the components physicians looked at for
25 their decision making.

1 **Q.** Now, Dr. Deer, I think you helped us prepare another
2 slide that identified some of the key developments in West
3 Virginia and nationally related to the changing standard of
4 care from the 1990s through the present; do you recall that?

5 **A.** I do recall that, yes.

6 **Q.** Okay.

7 MS. MAINIGI: Your Honor, I'm going to put a
8 demonstrative on the screen and let me explain to you what
9 it is.

10 Matt, if you could put -- put it up there.

11 What this is, Your Honor, is Dr. McCann -- this was an
12 admitted exhibit under Dr. McCann. It was, I think, a 1006
13 summary charge that Your Honor admitted. For the record,
14 it's P-44711_0009 and what it shows, according to Dr.
15 McCann, is the distribution of oxycodone and hydrocodone by
16 all distributors from 1997 to 2019.

17 BY MS. MAINIGI:

18 **Q.** Does this chart look familiar to you, Dr. Deer?

19 **A.** Yes, it does.

20 **Q.** Okay. So, we just talked about a few major events that
21 occurred. You just testified about the launch of OxyContin
22 and introduction of pain as the fifth vital sign in 1996; is
23 that correct?

24 **A.** That's correct.

25 MS. MAINIGI: So, Matt, let's add that to our

1 chart.

2 BY MS. MAINIGI:

3 Q. And then, you also testified about the VA's adoption of
4 pain as the fifth vital sign in 2000 and the Joint
5 Commission's adoption in 2001; is that correct?

6 A. That's correct.

7 MS. MAINIGI: So, let's add those to the chart.

8 BY MS. MAINIGI:

9 Q. And then, you just testified right now about the DEA
10 statement promoting pain relief?

11 A. That's correct.

12 MS. MAINIGI: And let's add that to the chart.

13 BY MS. MAINIGI:

14 Q. So, let's shift over to what was happening in West
15 Virginia in this time period. Let's take a look at
16 WV-01219, which is an admitted document. It was admitted
17 during Dr. Waller's testimony. What -- what is this
18 document, Dr. Deer?

19 A. This is a Board of Medicine statement clarifying the
20 use of opioids for the treatment of chronic non-malignant
21 pain.

22 Q. And I think if we turn to Page 2, we'll see the date on
23 this document. What is that date?

24 A. July 14th, 1997.

25 MS. MAINIGI: And let's go back to the first page

1 and let's take a look at the second paragraph, Matt, if you
2 could highlight that.

3 BY MS. MAINIGI:

4 **Q.** And if you could read that to us, Dr. Deer?

5 **A.** Happy to. The purpose of this statement is to clarify
6 the Board of Medicine's position on the appropriate use of
7 opioids for patients with chronic non-malignant pain so that
8 these patients will receive quality pain management and so
9 that their physicians will not fear legal consequences,
10 including disciplinary action by the board, when they
11 prescribe opioids in a manner described in this statement.
12 It should be understood that the board recognizes that
13 opioids are appropriate treatment for chronic non-malignant
14 patient in selected patients.

15 **Q.** So, first, let's just define chronic non-malignant
16 pain. What is that?

17 **A.** So, chronic pain is pain that lasts -- and it's been
18 defined different ways, but pain that lasts more than
19 12 weeks. Some people define that as chronic pain. Others
20 have described chronic pain as pain that lasts longer than
21 you would expect tissue healing to occur.

22 So, for example, if you have a trauma to your leg, you
23 would expect it to get better over time and it doesn't. And
24 you still have nerve abnormalities. So, that's two
25 definitions that are widely used.

1 **Q.** And non-malignant pain would mean non-cancer pain
2 basically?

3 **A.** Correct. That means your pain is not cancer-related
4 pain.

5 **Q.** So, before this time period, let's say before 1997,
6 were doctors generally prescribing opioid medications for
7 chronic non-malignant pain in their ordinary practice?

8 **A.** They were, but not -- not very often and not very high
9 doses. They were using short-acting drugs like Percocet,
10 Tylox, Dermabond. You know, and they were -- they were
11 afraid to go to higher doses because of fear of the Board of
12 Medicine taking their license if they gave too much
13 medication in those early days.

14 **Q.** So, what do you take from this statement issued by the
15 Board of Medicine in 1997? What's your interpretation of
16 that?

17 **A.** Well, I think it goes back to what was going on in the
18 country we've talked about a little bit. The fifth vital
19 sign came out, as far as recommendation from APS. Doctors
20 were starting to think that pain was a right. The World
21 Health Organization had said that it was right for cancer
22 pain. Then that was then transferred over to non-cancer
23 pain. And I think the Board of Medicine in West Virginia,
24 getting advice from doctors, we all thought that, you know,
25 longer-acting drugs may be better and safer. And from

1 people like the Federation of State Medical Boards that they
2 should be allowed treatment of pain because they thought it
3 was undertreated and undertreatment became -- became a big
4 fear then of doctors after this type of statement came out.

5 **Q.** Well, let's take a look at the fourth paragraph in this
6 document on the first page.

7 MS. MAINIGI: Matt, if you could blow that up.

8 BY MS. MAINIGI:

9 **Q.** So, that paragraph reads a physician need not fear
10 disciplinary action by the board if complete documentation
11 of prescribing of opioids in chronic non-malignant pain,
12 even in large doses, is contained in the medical records.
13 What do you take from that statement?

14 **A.** I take from this that, you know, this is one of the
15 things we talked about earlier. When I would get someone to
16 come in and see me after three years of pain treatment on a
17 really high dose, I think doctors felt comfortable just
18 going up on the dose rather than referring them to a
19 specialist. So, this is, I think, very -- a very common
20 practice of, you know, upping the dose until someone got
21 better or got a side effect.

22 **Q.** So, at the bottom of the first page there is a
23 suggested references section, and there are two articles
24 that are listed as references. Are you familiar with those
25 articles?

1 **A.** I'm very familiar with both those articles.

2 **Q.** And can you just summarize for me at a high level what
3 your understanding is of the point of those articles?

4 **A.** So, the Portenoy article is famous, famous in our
5 field, because Russell Portenoy, a neurologist in New York,
6 he had treated cancer patients for many years. He said that
7 you should keep upping your dose until you get the effect,
8 which would be --

9 MR. FITZSIMMONS: Judge, I'm going to object.
10 He's setting forth what the author of an article meant,
11 which is hearsay, and I don't see any foundation for him to
12 be doing that at this point. So, this is improper.

13 THE COURT: I will sustain that one, Ms. Mainigi.

14 MR. FITZSIMMONS: Thank you, Judge.

15 MS. MAINIGI: Your Honor, he -- well, I can
16 establish some foundation.

17 THE COURT: All right. Go ahead.

18 BY MS. MAINIGI:

19 **Q.** Dr. Deer, are you familiar with the Russell Portenoy
20 article?

21 **A.** I know the article well and the physician pretty well.

22 **Q.** And was it a seminal article in the treatment of pain
23 during this time period?

24 **A.** It was.

25 **Q.** Was it widely read and distributed?

1 **A.** It was.

2 **Q.** And did the West Virginia Board of Medicine cite it as
3 a suggested reference to physicians in West Virginia?

4 **A.** They did.

5 MS. MAINIGI: Your Honor, I think I've established
6 foundation. And I think this would fall under 703. The
7 question that I would come back to, with your permission to
8 pose to Dr. Deer is, could he describe at a high level the
9 gist of what Dr. Portenoy was saying in his article.

10 THE COURT: I don't think 703 makes it admissible.
11 He can -- he can refer to it as the basis of his opinion.
12 Can you get around it under one of the exceptions to the
13 hearsay rule?

14 MS. MAINIGI: Your Honor, I think we really just
15 need it for notice. We're not going for the truth of the
16 matter. We just -- it was notice to the medical and
17 healthcare community about what the standard of care was at
18 the time.

19 THE COURT: Which exhibit are we talking about
20 here? I've lost my place.

21 MS. MAINIGI: Oh, Your Honor, it's in your binder.

22 MR. FITZSIMMONS: 1219.

23 THE COURT: What's the number, the exhibit?

24 MS. MAINIGI: 1219, Your Honor, in the binder, and
25 you'll see it's a --

1 THE COURT: Well, hasn't it already been admitted?

2 MS. MAINIGI: The document -- let me just double
3 check. This document has been admitted. I'm just asking
4 him about the suggested references that the Board of
5 Medicine tells doctors in West Virginia to go look at. The
6 other point of that -- the other hearsay --

7 THE COURT: Just a minute.

8 MS. MAINIGI: Yes, Your Honor.

9 THE COURT: Mr. Fitzsimmons?

10 MR. FITZSIMMONS: Judge, this is a footnote and
11 she's now asking this witness to tell us what's in the
12 article. It's hearsay at its greatest.

13 THE COURT: I will sustain the objection, Ms.
14 Mainigi.

15 MR. FITZSIMMONS: Thank you, Your Honor.

16 MS. MAINIGI: Your Honor, if I might just --

17 THE COURT: He can -- he can refer to it as the
18 basis of his opinion, but I don't think he can get into the
19 substance of the -- of the article. I'll sustain the
20 objection.

21 MS. MAINIGI: Okay. Thank you, Your Honor.

22 BY MS. MAINIGI:

23 Q. Was this article from Dr. Portenoy, Dr. Deer, an
24 article that physicians during this time period could have
25 reasonably relied upon?

1 **A.** Many did.

2 **Q.** And could you elaborate on that, please?

3 **A.** Many physicians adopted the philosophy that you upped
4 the dose of opioids until someone got better, their pain
5 below a 3 or a 4, or they had a side effect. And there was
6 no ceiling, was what Dr. Portenoy always stated in his
7 lectures and things around the country. And so, you should
8 keep going up even to a thousand milligrams a day without
9 any fear of any problems in a patient. That was his
10 teaching and the article's gist.

11 **Q.** And how about the second article, is this an article
12 you're also familiar with, The Use of Opioids for the
13 Treatment of Chronic Pain: A Consensus Statement?

14 **A.** I am.

15 **Q.** And was that an article that was relied upon, to your
16 knowledge, by doctors in West Virginia in their prescribing?

17 **A.** I believe that it was.

18 **Q.** And in what direction did that article take them, as
19 far as prescribing?

20 **A.** Just for the Court's knowledge, these two societies, I
21 was members of both. They were the two largest pain
22 societies in the country at the time. They had a lot of, I
23 would say, older non-interventional physicians writing these
24 statements who were opioid experts and they both -- they
25 recommended that patients be treated with opioids, again, to

1 proper doses without side effects.

2 **Q.** So, did this Position Statement from the Board of
3 Medicine in West Virginia, did that get distributed to
4 physicians in West Virginia?

5 **A.** It did. I think all physicians in West Virginia
6 received that board policy.

7 **Q.** Okay. If I could ask you to turn to the next document,
8 which is WV-03003, can you identify this document for us,
9 please, Dr. Deer?

10 **A.** Yes. We now receive our Board of Medicine newsletters
11 via e-mail, but this was -- they used to mail this to all
12 the doctors licensed in West Virginia every quarter or this
13 was one for a year, it looks like, from January to December,
14 but it would come to all licensed physicians in West
15 Virginia.

16 **Q.** So, this went to all licensed physicians?

17 **A.** I believe so, yes.

18 **Q.** Okay. And if you turn to Page 6 of the document, which
19 is the very last page, at the top of that page, on the
20 right, it says board issues statement on the use of opioids
21 for the treatment of chronic non-malignant pain. To your
22 knowledge, was that the statement we were just looking at?

23 **A.** Yes, it was.

24 **Q.** Okay. And could you go ahead and read this, the rest
25 of this statement, please?

1 **A.** Certainly.

2 MR. FITZSIMMONS: Judge, I'm going to object to
3 having him read the news information into the record at this
4 point.

5 MS. MAINIGI: Your Honor, I can go ahead and move
6 this document into evidence. So, why don't I go ahead and
7 do that. And it would come under the ancient document
8 exception, Your Honor. Documents like this, also, this
9 newsletter, were actually admitted through Dr. Waller.

10 THE COURT: Any objection?

11 MR. FITZSIMMONS: I don't know what the date was,
12 Judge, on that.

13 THE COURT: This is '97. December of '97.
14 January --

15 MR. FITZSIMMONS: It doesn't make the date then, I
16 don't believe.

17 MS. MAINIGI: It does. January '98 is the cutoff.

18 MR. FITZSIMMONS: If it's January of -- if it is,
19 it is.

20 THE COURT: Well, let me look. Statement in a
21 document that was prepared before January 1st, 1998 and
22 whose authenticity is established. It's admitted.

23 MS. MAINIGI: Thank you, Your Honor.

24 BY MS. MAINIGI:

25 **Q.** So, Dr. Deer, could you just read that statement from

1 the board, please?

2 **A.** The Board's ad hoc committee on Americans with
3 disabilities had several meetings with interested parties on
4 the issue of pain management. At the July, 1997 meeting,
5 the full board approved the committee's Position Statement
6 on the use of opioids for the treatment of chronic
7 non-malignant pain. In September, 1997, the board mailed
8 its Position Statement to all physicians currently holding
9 an active medical license in the State of West Virginia. If
10 you are interested in receiving a copy of this Position
11 Statement, please contact the board.

12 **Q.** Thank you, Dr. Deer.

13 MS. MAINIGI: Matt, let's go back to our chart.

14 THE COURT: Just a minute. Just so the record
15 will be clear, I admitted the exhibit, DEF-WV-03003, under
16 the ancient documents records exception to the hearsay rule,
17 which is found in 803(16).

18 MS. MAINIGI: Thank you, Your Honor.

19 BY MS. MAINIGI:

20 **Q.** Dr. Deer, would you add the West Virginia Board of
21 Medicine statement from 1997 to this chart?

22 **A.** Oh, absolutely. It changed people's perceptions.

23 MS. MAINIGI: Matt, if we could go ahead and add
24 it, please. Oh, it's there. Sorry.

25 BY MS. MAINIGI:

1 Q. Dr. Deer --

2 MS. MAINIGI: Actually, Your Honor, would now be a
3 good time for a break before I turn to another document?

4 THE COURT: Yes, I think it would be.

5 You can step down during the break, Dr. Deer.

6 THE WITNESS: Thank you, sir.

7 THE COURT: We'll be in recess for about ten
8 minutes.

9 (Recess taken)

10 (Proceedings resumed at 10:38 a.m. as follows:)

11 MS. MAINIGI: Your Honor, I apologize. The
12 witness will be right out of the men's room.

13 THE COURT: That's all right. We usually check to
14 see if everybody is back, but this time we didn't do that.

15 (Pause)

16 Thank you, Dr. Deer.

17 BY MS. MAINIGI:

18 Q. All right, Dr. Deer, we left off in '97 in West
19 Virginia. Do you recall from 1998 something called the
20 Intractable Pain Act in West Virginia?

21 A. I recall it well.

22 MS. MAINIGI: I'm going to ask, Matt, if you could
23 put up on the screen 03106. And that is also in the binder.

24 BY MS. MAINIGI:

25 Q. What was the Intractable Pain Act? Let's start

1 with that, Dr. Deer.

2 **A.** So it was an act that talked about prescribing
3 medication for patients who had intractable pain.

4 **Q.** And what is intractable pain? What's that definition?

5 **A.** So intractable means that reasonable attempts have been
6 made to treat someone's pain. For example, I have an
7 overuse injury of my tendon in my ankle right now. And, so,
8 if I got to physical therapy, it didn't help me. If I had
9 injections, it didn't help me. If a medication didn't help
10 me, that would be intractable pain. It doesn't go away with
11 normal treatment.

12 **Q.** Is it similar to chronic pain?

13 **A.** Well, it can be chronic pain. So you can have chronic
14 pain -- let's say, for example, you're a lawyer and you sit
15 all day and your back hurts and it hurts you all the time,
16 that's chronic pain. But it may not be intractable because
17 you go home, you stretch, you get in the hot tub, you feel
18 fine. Right? So it's chronic pain but not intractable.

19 Intractable means it's so severe that you just can't
20 get rid of it and it affects your life, your, your psyche,
21 and everything about you. It becomes part of you almost.

22 MS. MAINIGI: Your Honor, this document that is
23 03106, which is the Intractable Pain Act from the West
24 Virginia legislature, I'd ask the Court to take judicial
25 notice of this document.

1 THE COURT: Any objection?

2 MR. FITZSIMMONS: No objection, Your Honor.

3 THE COURT: It's judicially noticed and admitted.

4 MS. MAINIGI: Thank you, Your Honor.

5 BY MS. MAINIGI:

6 Q. So taking a look at the, the document where it
7 starts with at the top "An act," could you read that,
8 please, Dr. Deer?

9 A. Yes. "An act to amend Chapter 30 of the Code of West
10 Virginia, one thousand nine hundred thirty-one, as amended
11 by adding thereto a new article, designated Article 3(a),
12 relating to limiting disciplinary actions against certain
13 health professionals prescribing, administering, or
14 dispensing controlled substances in the management of
15 intractable pain."

16 Q. So this -- the concept that's reflected in this act,
17 Dr. Deer, was that consistent with the '97 Board of Medicine
18 Physician Statement that we looked at earlier?

19 A. It was very consistent with what the Board of Medicine
20 had said a year earlier.

21 Q. And what was the goal here, to your understanding?

22 A. I think the goal was really intended to be a good goal
23 to, to treat people who needed treatment. So I think the
24 intent was, was, was, you know, at the time reasonable and
25 felt to be a need.

1 **Q.** And if we look at the bottom of the first page going on
2 to the second page, starting with "a physician shall not --"

3 MS. MAINIGI: And, Matt, why don't we go ahead and
4 highlight the relevant provisions there. The highlighted
5 portion I think would be Number 2.

6 BY MS. MAINIGI:

7 **Q.** So Number 2 refers to disciplinary sanctions --
8 that a physician would not be subject to disciplinary
9 sanctions by the state if the physician prescribed,
10 administered, or dispensed pain-relieving controlled
11 substances for the purpose of alleviating or controlling
12 intractable pain when, in the case of intractable pain
13 involving a patient who is not dying, the physician
14 discharges his or her professional obligation to relieve
15 the patient's intractable pain even though the dosage
16 exceeds the average dosage of a pain-relieving
17 controlled substance, if the physician can demonstrate
18 by reference to an accepted guideline that his or her
19 practice substantially complied with that accepted
20 guideline.

21 What do you take that to mean?

22 **A.** Well, I think it was telling physicians that if someone
23 had chronic pain that was non-cancerous, they still should
24 be treated like a cancer patient basically with higher doses
25 without fear of retribution against the doctor and if they

1 documented why they were doing it in their chart.

2 **Q.** And would you say that -- we just looked at that Board
3 of Medicine statement from '97 which had references to the
4 Portnoy article and others. Do you recall that?

5 **A.** I do.

6 **Q.** And would you say that an article like that was an
7 accepted guideline or reference for physicians at the time?

8 **A.** It became an accepted standard.

9 **Q.** Now, if we take a look at the last sentence there,
10 still under Number 2, it says evidence of non-compliance
11 with an accepted guideline is not sufficient alone to
12 support disciplinary or criminal action.

13 How do you take that sentence?

14 **A.** Well, --

15 MR. FITZSIMMONS: Judge, I'd like to lodge an
16 objection. This is a doctor who's now providing us with
17 legal opinions of legislation. It's outside the scope of
18 his expertise --

19 MS. MAINIGI: Your Honor, Dr. Deer discussed --

20 MR. FITZSIMMONS: -- as the question was phrased.

21 MS. MAINIGI: I'm sorry.

22 MR. FITZSIMMONS: As the question was phrased.

23 MS. MAINIGI: I can rephrase, Your Honor, but Dr.
24 Deer discussed the Intractable Pain Act.

25 THE COURT: I'll sustain the objection. You can

1 try another way, Ms. Mainigi.

2 MS. MAINIGI: Sure.

3 BY MS. MAINIGI:

4 Q. To your understanding, Dr. Deer, -- well, let's
5 step back. Did you look at the 1998 Intractable Pain
6 Act as part of formulating your expert opinion?

7 A. I did.

8 Q. And did you have an understanding of the Intractable
9 Pain Act in the time period in which this act was passed in
10 the course of your normal practice?

11 A. I did.

12 Q. And you went back and reviewed the Intractable Pain Act
13 as part of putting your report together?

14 A. That's correct.

15 Q. And you've relied on the Intractable Pain Act in
16 formulating your opinions?

17 A. One of the things I relied on.

18 Q. This last sentence that, that we've referred to, did
19 you form an impression in the course of formulating your
20 opinions as to what you understood that last sentence to
21 mean?

22 A. The last sentence, in my opinion, means that the doctor
23 didn't have to follow the guidelines, whatever the
24 guidelines were, and still may not get in any trouble
25 because I think the board was saying the guidelines had not

1 caught up with current treatment standard of care. This was
2 how I took it at the time.

3 **Q.** Do you understand -- do you have an understanding of
4 what motivated the passage of the Intractable Pain Act?

5 **A.** I think many factors including, you know, the, the
6 overall thought process throughout West Virginia and the
7 country that patients had the right to be treated for
8 chronic pain. And intractable pain, which was severer pain,
9 was the highlight of that focus.

10 **Q.** Let's go back to your chart, Dr. Deer. Should we go
11 ahead and add the Intractable Pain Act to your chart?

12 **A.** I think it is a factor.

13 **Q.** Now, let me show you next from West Virginia in 2001
14 something called the Joint Policy Statement on Pain
15 Management at the End of Life. And that is 02413.

16 What was this Joint Policy Statement? Let's start with
17 this. Who was issuing this Joint Policy Statement?

18 **A.** It was the West Virginia Boards of Examiners of
19 Registered Professional Nurses, Medicine, Osteopathy, and
20 Pharmacy.

21 **Q.** And is there a date on the document that we see?

22 **A.** I don't see the date.

23 **Q.** I think if you turn to --

24 **A.** There we go.

25 **Q.** -- the last page.

1 **A.** January through March. It was approved January through
2 March of 2001.

3 **Q.** And is this a statement you were familiar with at the
4 time the statement came out?

5 **A.** Yes, it was.

6 **Q.** And is this a statement that you reviewed again in the
7 course of formulating your opinions here today?

8 **A.** Yes, I did.

9 MS. MAINIGI: Your Honor, at this time I'd like to
10 move to admit 02413 into evidence.

11 THE COURT: Is there any objection?

12 MR. FITZSIMMONS: No objection, Your Honor.

13 THE COURT: It's admitted.

14 BY MS. MAINIGI:

15 **Q.** So let's take a look at a few portions of this
16 policy statement from the various boards in West
17 Virginia.

18 If we turn to the second page, there is a heading
19 entitled "Management of Pain."

20 Now, I'm going to ask you to focus on the highlighted
21 sections. What do the highlighted portions of this document
22 tell doctors about the role of opioids in pain management?

23 **A.** Well, it tells them, first of all, you have to assess
24 whether someone is in pain, which I think is smart. You
25 should always do that. You need to treat it promptly.

1 And then, and then it goes from there to the need to
2 recognize if someone becomes tolerant.

3 And for the Court, tolerance means you need more of
4 anything to get the same effect. That's tolerance.

5 And physically dependent, which means that if you quit
6 taking something, you have symptoms of withdrawal. And that
7 that happens with every opioid patient over time, and that
8 that has nothing to do with addiction which is abnormal
9 behavior to get a drug.

10 THE COURT: Doctor, let me ask you a question.

11 What's the difference between physical dependence and
12 addiction?

13 THE WITNESS: So physical dependence means if
14 you're taking a medication -- like say, for example, someone
15 who took Xanax at bedtime for anxiety and they quit taking
16 the medication and they had a seizure or they felt sweaty
17 and felt bad, that's physical dependence. The body is used
18 to that. The receptors are full of that drug. And when the
19 drug is gone, they, they feel the physical effects of it.

20 They're not -- once they get through that, that phase,
21 they don't crave the drug. So that means they were
22 dependent upon it physically, but they didn't have an
23 abnormal craving unrelated to a medical issue.

24 If they're addicted to Xanax like, unfortunately, many
25 high school students have become, they take it for reasons

1 other than anxiety. They take it for reasons like to get
2 high.

3 And when they, when they quit taking it, they crave it.
4 They're not -- because they're in withdrawal. They crave it
5 because they need it psychologically. And they would steal,
6 rob, break into your house, do whatever they can do to get
7 the drug.

8 THE COURT: Thank you, sir.

9 THE WITNESS: Yes.

10 BY MS. MAINIGI:

11 **Q.** And, so, the, the last sentence that's highlighted,
12 what do you take that to mean, Dr. Deer?

13 **A.** Let me read it first to refresh myself.

14 (Pause)

15 So it's saying that governmental policies that were
16 intended for -- to stop diversion of drugs should not
17 interfere with the doctor prescribing medications at the end
18 of life.

19 So, therefore, you would maybe prescribe medicines you
20 wouldn't normally prescribe in that patient because they're
21 in a terminal condition either at their home or in a
22 hospice.

23 **Q.** Okay. Now I'm going to ask you to take a look at
24 another policy statement, this time just from the West
25 Virginia Board of Medicine related to the use of opioids in

1 treating other types of pain. This is from 2005. So it is
2 MC-WV-1218. This document was already admitted under Dr.
3 Waller.

4 So this policy statement, Dr. Deer, does this -- does
5 it limit itself to a particular circumstance, the policy for
6 the use of controlled substances for the treatment of pain?

7 **A.** I believe this policy was about non-cancer pain as well
8 as cancer pain.

9 **Q.** And who issued this policy statement?

10 **A.** The Board of Medicine.

11 **Q.** Was this -- I'm sorry.

12 **A.** In West Virginia.

13 **Q.** Would this policy statement have been distributed to
14 doctors in West Virginia?

15 **A.** Yes. If you had a license to practice medicine here,
16 whether you lived here or outside the State of West
17 Virginia, you would have received this newsletter.

18 **Q.** So if we take a look at the first page and the last
19 sentence of the first paragraph, what types of pain
20 treatment did the board define as inappropriate treatment of
21 pain?

22 **A.** So this, this board recommendation told doctors that if
23 you had a patient complain of pain and you didn't treat
24 their pain or if you didn't treat them enough, if you were
25 under-treating their pain, or if you over-treated their

1 pain, or if you offered them ineffective treatment that you
2 kept doing over and over again, all of those were forms of
3 inappropriate treatment.

4 **Q.** And if you look at the last paragraph on the first
5 page, and I think the last sentence that starts with "as
6 such," so the, the inappropriate treatment of pain included
7 under-treatment; is that correct?

8 **A.** That's correct.

9 **Q.** And, so, what do you take from this last sentence about
10 board action?

11 **A.** So in '97 we talked about the board saying you can give
12 more medication without fear if you document the select
13 patient. And here the board said if you under-treat with
14 opioids, basically you would be investigated. And it led to
15 many complaints at that time against doctors for
16 under-treatment of pain.

17 **Q.** In your experience here in West Virginia during this
18 time period, was this a real concern for physicians being
19 investigated for the under-treatment of pain?

20 **A.** It was for some, I mean certainly not for all, but it
21 was for some. In fact, I was, as I said earlier, asked
22 sometimes to comment in a hospital about someone
23 under-treating someone and to review a chart and give an
24 opinion.

25 **Q.** Now, let's flip over to the second page, Dr. Deer,

1 please, and that first sentence at the top of that page.

2 What do you understand the board to be saying there?

3 **A.** That the board recognized that opioids, controlled
4 substances, may be essential to treat both acute pain, so
5 when you break your leg or fall off a scaffolding; after
6 surgery, so when you have your appendix removed; chronic
7 pain, which we've defined, whether due to cancer or
8 non-cancer origins.

9 **Q.** So the board was saying that opioids were essentially
10 appropriate for the treatment of all kinds of pain?

11 **A.** It was basically a reinforcement of the 1997 statement
12 expanding a bit to include all types of pain.

13 MS. MAINIGI: Now, Matt, if we can come back to
14 the chart.

15 BY MR. FITZSIMMONS:

16 **Q.** Dr. Deer, can we go ahead and add this 2005 Board
17 of Medicine policy statement to the chart?

18 **A.** I believe that we would, yes.

19 **Q.** Now, we've been focusing on actions from the Board of
20 Medicine and other boards from West Virginia from '97, 2001,
21 and 2005.

22 To your understanding and knowledge, was West Virginia
23 the only Board of Medicine in the country that was issuing
24 guidelines and policies like this at the time?

25 **A.** No, not at all.

1 **Q.** What did you understand was happening in the rest of
2 the country?

3 **A.** Well, so there was a, a group called the Federation of
4 State Medical Boards that gave advice to medical boards
5 around the country. And many of those boards adopted those
6 recommendations. So I think West Virginia was, along with
7 many other boards, creating the same types of policies.

8 **Q.** And the guidelines from the Federation of State Medical
9 Boards just -- those also have an impact on physician
10 prescribing in West Virginia?

11 **A.** They do in West Virginia for sure because certainly
12 some of the, some of the materials that the Federation of
13 State Medical Boards published were given to West Virginia
14 physicians.

15 **Q.** And how do you know that?

16 **A.** Because I received a copy of the book Dr. Fishman wrote
17 as part of that process of Federation of State Medical
18 Boards.

19 **Q.** And we'll come back to Dr. Fishman's book in a second.

20 Now, in the binder, then, I think, just for the purpose
21 of the record, I think the Federation model guidelines were
22 covered with Dr. Gilligan who was here on Friday. So we're
23 going to skip over those with you. But those are, for the
24 purpose of the record, 02937 and 03605.

25 So let's stick with the West Virginia Board of Medicine

1 in 2005. And I'm going to ask you to look at 3010. And
2 it's another West Virginia Board of Medicine quarterly
3 newsletter.

4 And I'm going to ask you to turn to Page 5 of this
5 newsletter, please.

6 Page 5 of this newsletter is a letter to the head of
7 the DEA from, among other Attorney Generals, the Attorney
8 General of the State of West Virginia, Darrel McGraw. There
9 are multiple Attorney Generals that sent a letter to the
10 head of the DEA.

11 Have you had a chance to review this letter?

12 **A.** Yes, I have.

13 **Q.** What is your understanding of the gist of the letter?

14 **A.** Well, so they write a letter to Ms. Tandy who I had the
15 chance to meet. She was the Director of the DEA under
16 President Bush.

17 **MR. FITZSIMMONS:** Judge, I'm going to lodge an
18 objection as to him interpreting the Attorney General's
19 letter as to what it means to him.

20 **MS. MAINIGI:** Your Honor, I think it was notice to
21 him and other doctors in West Virginia because the letter
22 was published in the Board of Medicine newsletter which went
23 to all licensed physicians in West Virginia. They received
24 the newsletter and had an opportunity to review the letter
25 that the AG sent to the DEA and interpret the meaning of the

1 letter.

2 THE COURT: Can't he testify as to what -- his
3 understanding of what the, what the letter meant to him,
4 Mr. Fitzsimmons?

5 MR. FITZSIMMONS: It's hearsay, Judge, for him to
6 get up here and interpret that this is -- it's hearsay.
7 It's an out-of-court declaration that's being offered at
8 this time. She said notice but it's for the truth as to
9 what's in there.

10 MS. MAINIGI: Your Honor, --

11 MR. FITZSIMMONS: It's improper.

12 MS. MAINIGI: I'm sorry. Go ahead.

13 MR. FITZSIMMONS: I think that's totally improper,
14 Your Honor.

15 MS. MAINIGI: Your Honor, it is not offered for
16 the truth of the statement at this point. It is purely
17 offered as notice, as many of these documents were that came
18 in through Dr. Gilligan and many other experts here, of
19 notice to the healthcare community of what was happening in,
20 in the world, essentially, in their location with respect to
21 the standard of care.

22 I also think under 902(5) this newsletter is a
23 publication that's issued by a public authority and is
24 self-authenticating. So I think the authenticity is
25 established. But hearsay -- this is being offered purely

1 for notice, Your Honor. And it is also expert reliance
2 materials, Your Honor.

3 THE COURT: Well, 902 just authenticates it. It
4 doesn't get around the hearsay problem if I understand it.

5 MS. MAINIGI: No. And on the hearsay issue, Your
6 Honor, it's just notice to the healthcare community. And it
7 is part of the reliance materials that Dr. Deer relied upon.

8 THE COURT: Well, I'll let him testify as to what
9 it is and who it was sent to if he knows. Beyond that, I'll
10 sustain the objection.

11 BY MS. MAINIGI:

12 **Q.** Dr. Deer, what is your understanding of the gist of
13 the letter from the Attorney General of West Virginia to
14 the head of the DEA?

15 **A.** So --

16 MR. FITZSIMMONS: I'm going to object. I think
17 that's the same exact question I objected to.

18 THE COURT: Yeah. I'll sustain the objection to
19 that question.

20 MS. MAINIGI: Your Honor, then I misunderstood
21 what you were going to let him testify to. Could you repeat
22 that, please?

23 THE COURT: Well, maybe I made myself unclear.
24 But I think he can testify as to what it is and who it was
25 sent to and that's about it, what his understanding of the

1 purpose of it was.

2 MS. MAINIGI: Thank you, Your Honor.

3 THE COURT: But don't get into the substance
4 because I think the substance is hearsay.

5 MS. MAINIGI: Okay. Thank you, Your Honor, for
6 that clarification.

7 BY MS. MAINIGI:

8 Q. Dr. Deer, could you tell us what your understanding
9 was of the purpose of the letter?

10 A. Yes. The purpose was to communicate to the DEA
11 concerns of the Attorney Generals around the country about
12 opioid prescribing and limitations therefore.

13 Q. And, specifically, what about opioid prescribing and
14 limitations?

15 A. That was a concern. They felt the state had the same
16 responsibility to oversee it and the federal government was
17 overseeing it, and there was communication about who should
18 be overseeing it.

19 Q. And the -- did the Attorneys General express a view as
20 to what the DEA should be doing?

21 A. They felt that the shift was more towards
22 anti-diversion and it should be more towards treatment.

23 Q. Thank you. Let's see.

24 MS. MAINIGI: Your Honor, at this time I would
25 like to move for the admission of 3010 into evidence.

1 THE COURT: Which one is that?

2 MS. MAINIGI: It's the newsletter that we've been
3 talking about, Your Honor, and the --

4 THE COURT: I've got that.

5 Do you have any objection to that, Mr. Fitzsimmons?

6 MR. FITZSIMMONS: Judge, I believe you sustained
7 the objection I had previously made.

8 THE COURT: Well, I think I did.

9 MS. MAINIGI: The objection was sustained, Your
10 Honor, as I understood it, as to the question. But news
11 letters like this were actually introduced into evidence
12 with Dr. Waller, for example, as well as several other
13 witnesses and --

14 THE COURT: Well, it comes in for the limited
15 purpose of notice but not for the truth. Is that right?

16 MS. MAINIGI: That's correct.

17 THE COURT: Well, I'll admit it for the limited
18 purpose.

19 MS. MAINIGI: Thank you, Your Honor.

20 BY MS. MAINIGI:

21 **Q.** So we talked earlier about the 1998 Intractable
22 Pain Act. Do you recall that, Dr. Deer?

23 **A.** I do.

24 **Q.** And do you recall that in 2009 the West Virginia
25 legislature amended the Intractable Pain Act?

1 **A.** I do.

2 **Q.** Let me ask you to take a look at 3067 which is the 2009
3 Management of Pain Act. Are you familiar with that act, Dr.
4 Deer?

5 **A.** Yes, I am.

6 **Q.** And did you rely on that act in the course of forming
7 your opinions here today?

8 **A.** I did.

9 **Q.** And were you familiar with the act at the time it was
10 passed in 2009?

11 **A.** I was.

12 MS. MAINIGI: Your Honor, I'd like the Court -- to
13 ask the Court to take judicial notice of 03067.

14 THE COURT: Any objection?

15 MR. FARRELL: Not to you taking judicial notice,
16 Judge.

17 I would like to place on the record, aside from the
18 examination of this witness, that the subject of some of
19 these questions was the subject of motions *in limine* and
20 *Daubert* motions by the defendants prior to trial.

21 And, in fact, you struck one of our expert witnesses
22 from the DEA who was going to testify about the Controlled
23 Substances Act.

24 So I would just like to note my continued objection to
25 witnesses in this court being served as legal experts.

1 MS. MAINIGI: Your Honor, --

2 THE COURT: Well, --

3 MS. MAINIGI: -- we don't agree with that
4 statement. This is a -- this is a standard of care expert.
5 And these acts in West Virginia obviously served the purpose
6 of modifying the standard of care for West Virginia
7 physicians, of which Dr. Deer is one.

8 THE COURT: The 03067 is judicially noticed and
9 admitted.

10 BY MS. MAINIGI:

11 **Q.** Dr. Deer, if you'd take a look at the top of that
12 document that references the act. It says "an act" and
13 then it goes on to describe it.

14 Can you just basically explain to us what your
15 understanding is of what the legislature did here?

16 MR. FITZSIMMONS: Judge, I'm going to object to
17 him giving legal opinions as to the legislature.

18 MS. MAINIGI: Your Honor, he's doing this from his
19 point of view as an expert on standard of care and a West
20 Virginia treating physician who had to at the time interpret
21 what the legislature was doing vis-à-vis this act.

22 THE COURT: I'll overrule the objection. I think
23 he can refer to it as a basis for his expert opinion. Go
24 ahead.

25 THE WITNESS: They took the word "intractable" out

1 of the previous legislation. We updated it with the word --
2 just chronic pain. So they made it easier to treat patients
3 who didn't have severe pain.

4 BY MS. MAINIGI:

5 **Q.** Was the '98 legislation related or limited to
6 intractable pain?

7 **A.** That's correct.

8 **Q.** And this 2009 legislation was amended to apply to all
9 pain?

10 **A.** They took the word "intractable" out of this
11 legislation.

12 THE COURT: Yeah. I think this is admissible.
13 He's -- his testimony is the course of the changes of the
14 standard of care over time and I think that his testimony
15 here is relevant to that. So the objection is overruled.

16 MS. MAINIGI: Thank you, Your Honor.

17 And just for the purpose of the record, to respond to
18 Mr. Farrell's objection further, I'll just note for the
19 record that, as we know, there were a number of company
20 witnesses that were called by the plaintiffs to come and
21 testify in this matter.

22 And the plaintiffs, in the course of all of that
23 testimony, elicited a number of -- posed a number of
24 questions and elicited testimony about those individual lay
25 person witnesses' understanding of DEA regulations as well

1 as the CSA.

2 BY MS. MAINIGI:

3 Q. You can put that document away, Dr. Deer.

4 And let's take a look at another joint statement issued
5 in 2010. And that is 2414.

6 We had earlier looked at a 2001 joint statement on pain
7 management from a number of boards in West Virginia; right?

8 A. Correct.

9 Q. Okay. And in 2010 there seems to be a reissuance of
10 the 2001 joint statement. If you go to Page 4 of 2414, what
11 is the date of the adoption?

12 A. March 12, 2001, initially but re-adopted May 10th,
13 2010.

14 Q. And are you familiar with this 2010 joint policy
15 statement, the re-adoption of the 2001 statement?

16 A. Yes, I am.

17 Q. To your understanding, did this re-adoption encourage
18 or discourage prescribing of opioids?

19 A. It encouraged prescribing of opioids.

20 MS. MAINIGI: Your Honor, just, just as the
21 earlier joint policy statement was admitted, I'd like to
22 move for the admission of 2414, please.

23 THE COURT: Any objection to this one?

24 MR. FITZSIMMONS: No objection, Judge.

25 THE COURT: It's admitted.

1 BY MS. MAINIGI:

2 Q. Let's go back to our chart, Dr. Deer. And in your
3 chart would you add the 2009 Management of Pain Act as
4 well as the 2010 joint policy statement?

5 A. I would.

6 Q. So, Dr. Deer, we've looked at a number of, of
7 statements and policies and acts from West Virginia. Do you
8 have an opinion on the relationship between the standard of
9 care for prescribing opioids for the treatment of pain and
10 all of the West Virginia laws and policies that we've been
11 discussing?

12 A. I think there's no doubt that the things on our graph
13 to the board changed the standard of care in West Virginia.

14 Q. In what manner?

15 A. It led to increased opioid prescribing around the
16 state.

17 Q. And do you have an opinion on whether West Virginia
18 prescribers, in fact, prescribed opioid medications more
19 freely in accordance with the guidance that was issued by
20 the various bodies in West Virginia?

21 A. I felt certain they did. And I saw it personally in
22 the referral base that we have. As those acts became law,
23 we saw patients getting sent to us with more and more
24 opioids.

25 Q. And do you have an opinion on whether doctors who in

1 accordance with this guidance issued in West Virginia, those
2 doctors who more freely prescribed opioid medications to
3 their patients, were they acting reasonably based on the
4 information available to them at the time?

5 **A.** I think at the time, the vast majority of those doctors
6 were acting within reasonable medical standards and standard
7 of care.

8 **Q.** And does that include the doctors who formed your
9 referral base, so the family doctors that referred patients
10 to you at the time?

11 **A.** I would say that the family doctors referred to me and
12 followed along those guides and treated patients with
13 high-dose opioids sometimes for many years before they sent
14 someone to see me because that was the tools they understood
15 at that time.

16 **Q.** Now, you, you referenced Dr. Fishman earlier. And one
17 thing we've not discussed yet is physician education.

18 Do you have an opinion as to whether physician
19 education played a role in the standard of care for pain
20 treatment?

21 **A.** So physician education -- and it's something called
22 continuing -- for the Court, continuing medical education is
23 something we all have to do to keep our license updated.

24 So every physician has to undergo continuing education.
25 And part of that required education in West Virginia became

1 education on pain. So it definitely made an impact overall
2 as we got near 2010.

3 **Q.** Now, did Dr. Fishman teach at various continuing
4 medical education events in West Virginia, to your
5 knowledge?

6 **A.** He taught in person at a state medical association
7 sponsored seminar on pain. And he also taught via video
8 because every doctor in West Virginia at one point had to
9 watch his lecture to recertify their license.

10 **Q.** And are you familiar with Dr. Fishman's book,
11 Responsible Opioid Prescribing?

12 **A.** I am.

13 MS. MAINIGI: And I believe, Your Honor, just for
14 the purpose of the record, this book was admitted during Dr.
15 Waller's testimony and is 02111.

16 BY MS. MAINIGI:

17 **Q.** Was this book disseminated to doctors in West
18 Virginia?

19 **A.** It was.

20 **Q.** And did the West Virginia -- in addition to inviting
21 Dr. Fishman to come speak in West Virginia, did the West
22 Virginia Board of Medicine promote Dr. Fishman's teachings
23 in both -- essentially into early 2010?

24 **A.** At that time, based on my recollection, in order to
25 renew yourself, you had to receive a lecture from

1 Dr. Fishman on opioid prescribing, a lecture from me on
2 procedures. I think there was a third lecture. I can't
3 remember what that was. I think it was three hours of CME
4 and I can't recall the third lecture. But you had to go
5 on-line and watch that or go to an in-person event.

6 **Q.** And do you have an opinion on the impact that, that the
7 CMEs that Dr. Fishman and others were involved with, what
8 impact that had on doctors in West Virginia regarding the
9 prescribing of opioids?

10 **A.** CME impacts your -- based on the evidence provided by
11 the speaker. So, you know, I think any CME that's well done
12 is going to be impactful based on the evidence that that
13 person chooses to present.

14 **Q.** And, again, doctors who prescribed in accordance with
15 the standard of care articulated at these CMEs and in
16 Dr. Fishman's book, in your opinion were they acting
17 reasonably in light of the information available to them at
18 the time?

19 **A.** At the time of that decision-making process from the
20 physician, yes.

21 **Q.** Now, I want to shift over to demographics in West
22 Virginia, Dr. Deer.

23 Do you have an opinion on whether demographics in West
24 Virginia had an effect at which -- had an effect on the rate
25 at which opioids were prescribed by West Virginia

1 physicians?

2 **A.** I believe that it had a large impact on prescribing in
3 West Virginia versus other places.

4 **Q.** And did you assist us in preparing a slide that
5 summarized those factors?

6 **A.** I did.

7 MS. MAINIGI: Matt, if we could put that on the
8 screen, please.

9 BY MS. MAINIGI:

10 **Q.** Were these the factors you noted in your report and
11 on the slide?

12 **A.** I think those are all the factors but one.

13 **Q.** Well, let's go through the, the factors.

14 What do you mean that higher rates of chronic pain had
15 an effect on higher opioid prescribing in West Virginia?

16 **A.** If you look at the demographic data, West Virginians
17 have more arthritis than any other state I believe. We
18 have -- I think we're third in obesity, and obesity has been
19 linked very closely to chronic pain.

20 For example, if you gain four pounds -- if you gain
21 one pound, it puts four pounds of weight on your spine and
22 your knees and your hips. So it's important.

23 We also have a higher rate of chronic pain among
24 smokers with vascular disease.

25 So there are many factors that leads to our chronic

1 pain rate being higher. We'll get to some of other ones
2 over the next three bullet points we have here.

3 **Q.** And -- well, let's, let's move to the second. Tell me
4 about the older population in West Virginia and how that
5 contributes to higher opioid prescribing.

6 **A.** Well, we're on average four years older than other
7 states. We have young people like Mike there that's leaving
8 the state for jobs and old people staying. And we have a
9 death rate that's greater than the birth rate so -- less
10 than the birth rate.

11 So we're, we're older. We're getting older. And if
12 you look at data, the older population has a higher risk of
13 chronic pain diseases.

14 **Q.** And then your, your third example is that there are
15 more injuries with more workers in physically demanding jobs
16 in West Virginia which also leads to higher opioid
17 prescribing. Explain that.

18 **A.** Well, we're a tough group of people in West Virginia,
19 you know. And back in the days from '94 to probably about
20 2008, we had a lot of coal miners being injured. We don't
21 have as many now, unfortunately for jobs. But we also had
22 timbering and plants and construction.

23 So we have a, we have a blue collar work force that
24 works really hard. And if you look at the data on that,
25 they get injured more than physicians and attorneys get

1 injured and need treatment. And many times they were
2 treated with opioids.

3 **Q.** And the last factor you list is insurance policies.
4 Can you explain what you mean by that?

5 **A.** Well, again, many physicians that are specialists don't
6 accept West Virginia Medicaid. I do. I grew up with not
7 much money, so I always feel it's my need to take care of
8 everyone.

9 And a lot of times we can't get approval for innovative
10 therapies because of the budget of Medicaid, and other
11 insurers too, Workers' Compensation, you know, public
12 employees. Sometimes it's limited to what you can do and I
13 think that sometimes led to a denial of referral to a
14 specialist, whether it be a pain specialist or a
15 neurosurgeon. And that, that patient stayed in the primary
16 care specialist's office on medication. So I think all
17 these factors played a role.

18 **Q.** And, so, how did that translate into West Virginia --
19 West Virginia residents perhaps having a higher rate of
20 opioid prescribing?

21 **A.** I think all those factors together led the primary care
22 specialists particularly to start people on opioids. And
23 then they stayed on those medications sometimes for life
24 once they were on them.

25 **Q.** Thank you, Dr. Deer. We can take that down.

1 Now, we spent a long time on your first phase. Let's
2 shift over to the second phase of the standard of care that
3 you mentioned earlier in your overview.

4 Just remind us briefly what the second phase is.

5 **A.** So I think in 2010 we started seeing a real peak in
6 people on high doses of opioids in the state. I know that
7 personally because they were sent to see me and I accepted
8 them as patients. So it got pretty bad.

9 And we also had a need to I think determine what a pain
10 clinic was. So around 2011 we started seeing changes to try
11 to turn the situation back towards therapies other than
12 opioids.

13 **Q.** And I think you referred to the second phase as
14 balancing. Explain that to us.

15 **A.** Well, I think the pendulum has swung so far to the
16 pro-opioid side by physicians' prescribing habits that it
17 became very, very difficult to understand what to do with
18 some of these patients who still were in severe pain despite
19 high-dose opioids.

20 So there was a movement by I think several parties to
21 try to figure out ways to allow treatment but be more
22 balanced and try to think of ways to use other therapies
23 other than opioids. So -- and to control better how those
24 were prescribed.

25 **Q.** Now, in 2012 there was legislation passed called the

1 CSMP and Chronic Pain Clinic Licensing Act. Are you
2 familiar with that legislation?

3 **A.** Yes, I am.

4 **Q.** Okay. And did you tell us earlier that you served on a
5 committee related to the CSMP?

6 **A.** I did.

7 **Q.** And was that a committee associated with this
8 legislation?

9 **A.** It was.

10 **Q.** Let me ask you to take a look at 03105.

11 MS. MAINIGI: And for the purpose of the record,
12 this is Senate Bill 437 which was actually admitted during
13 Dr. Gupta's testimony.

14 BY MS. MAINIGI:

15 **Q.** Now, did this law impose new requirements on
16 doctors?

17 **A.** It did.

18 **Q.** If you take a look at Page 19 of the act, do you see
19 the heading -- and 19, just for everybody's benefit, I'm
20 going by the page numbers on the lower left.

21 MS. MAINIGI: And if we could focus on the very
22 bottom of Page 19, Matt.

23 BY MS. MAINIGI:

24 **Q.** So is one of the things this act did, Dr. Deer, did
25 it require doctors to check the Controlled Substances

1 Monitoring Program before prescribing opioids to certain
2 patients?

3 **A.** It did.

4 **Q.** And did that requirement exist before this law was
5 passed?

6 **A.** There was no requirement before this law was passed.

7 **Q.** And what did that help with if a doctor was consulting
8 and, and by law was told to consult the CSMP before
9 prescribing opioids?

10 **A.** I think it really helped with doctor-shopping, if you
11 will, because if they were receiving medication from other
12 doctors and the doctor had to check that data bank, they saw
13 that before they prescribed a controlled substance. So it
14 helped with the issue if patients went to multiple doctors
15 for the same type of drug.

16 **Q.** So did that mean, as a hypothetical, a patient who went
17 to see three different physicians and got controlled
18 substances prescriptions from all three physicians, that
19 that patient may not be able to do that anymore since these
20 doctors were required to check the CSMP?

21 **A.** Well, it certainly -- the first person may not have
22 seen it, but the next two should have seen it if it was
23 reported by the pharmacy who filled the prescription to the
24 pharmacy board.

25 **Q.** And the act did a couple of other things too.

1 If you turn to the prior page, Page 18 at the very
2 bottom, there's a reference at the bottom to the Review
3 Committee making determinations on a case by case basis on
4 specific unusual prescribing or dispensing patterns
5 indicated by outliers in the system for abnormal or unusual
6 usage patterns of controlled substances.

7 What is your understanding of what this act required in
8 this regard?

9 **A.** It required the Board of Pharmacy to create a committee
10 to look at abnormal prescribing by doctors.

11 **Q.** And what was the committee looking for?

12 **A.** People that were outliers and the amount of medicine to
13 individuals, as well as people who were prescribing to --
14 you know, people that were actually in the same family.
15 They were looking at people who had deaths. The medical
16 examiner was part of this committee. So if there was a
17 death and there was a high prescriber with a lot of death
18 rates, those sort of issues.

19 **Q.** And what would -- would there be contact made with some
20 of the doctors who were reviewed? What would happen?

21 **A.** So, as I said earlier, Mr. Goff ran that committee that
22 I was on. So we reviewed every two months all the data. So
23 if a doctor had a death and they were prescribing a
24 controlled substance to that patient, they received a letter
25 from our committee that they needed to review their

1 prescribing habits.

2 We didn't say they caused their death, but it certainly
3 let them know that we were aware of the death and we wanted
4 them to look. And, of course, some doctors received
5 multiple of those letters, you know. And, certainly, that
6 was a big issue for the Board of Pharmacy Oversight
7 Committee.

8 Then they looked at were people prescribing multiple
9 classes of drugs to the same person because that can also be
10 an issue.

11 And then people that had more than five doctors
12 prescribing to them, all those doctors received a letter
13 from this committee saying that you have a patient -- they
14 should have seen it themselves from the Board of Pharmacy
15 check. But they got a letter saying you have a patient
16 who's seeing more than three physicians for a controlled
17 substance and they were asked to review their chart.

18 So it was all informational to them initially what was
19 going on in their practice in case they were in need of
20 education.

21 **Q.** And, so, the CSMP, coming back to that database for a
22 moment, the CSMP database was accessible by physicians; is
23 that right?

24 **A.** Every time you see a patient, you could access that
25 with your password of what the patient had received from

1 other physicians and from yourself.

2 **Q.** But the general public could not access the CSMP?

3 **A.** I think that would be a HIPAA violation for the general
4 public to access what a patient was given.

5 **Q.** And the third thing this act did -- I think you
6 referred to it earlier, Dr. Deer -- is there were provisions
7 in the act related to pain management clinics. Do you
8 recall that?

9 **A.** I do.

10 **Q.** And what do you understand the act to include with
11 respect to pain management clinics?

12 **A.** So there were people who were family doctors calling
13 themselves a pain clinic who had no training. And if they
14 were prescribing more than 51 percent of their patients a
15 controlled substance, then they would fall under this act.

16 And what that led to -- and, again, I remember the
17 committee that helped draft this law. They would go out and
18 be certified then. And they had many things they had to
19 meet as a criteria. It was really a way to get better
20 control of some of these centers that were really not doing
21 the right types of therapy for patients.

22 **Q.** So was there a licensing requirement and an inspection
23 requirement?

24 **A.** If you had over 51 percent of your patients on a
25 controlled substance, that was true. If you didn't meet

1 that criteria, you were excluded from that. But physicians
2 who had more than 51 percent of their patients receiving a
3 controlled substance were inspected and were either licensed
4 or told to desist in their treatment.

5 **Q.** So these three elements of the 2012 act, to your
6 understanding, what was the intended effect of these new
7 requirements?

8 **A.** It was to, I believe, to look at the prescribing habits
9 of physicians to try to get a handle on who actually was
10 treating pain in a more exact fashion and a more appropriate
11 way. So that was kind of the main gist of this act I
12 believe.

13 **Q.** And was there -- now, this act, did it limit in any way
14 the amount of opioids a physician could prescribe?

15 **A.** It didn't limit the amount at all. It was a first
16 step, though, I think toward the balancing as I talked
17 about.

18 So, you know, in '11 the secession began. In '12 this
19 happened. That was the first step. It was a good step
20 towards improving things. It still didn't limit the doses
21 that people could prescribe to patients without looking at
22 other options.

23 MS. MAINIGI: Matt, if we could put our chart back
24 up.

25 BY MS. MAINIGI:

1 **Q.** And, Dr. Deer, should we add this 2012 legislation
2 to your chart?

3 **A.** I would.

4 **Q.** Now, third phase of the standard of care that you
5 referenced, you said that was approximately 2015 to today.
6 Can you just again briefly describe that phase for us?

7 **A.** So I think this is the most important phase as far as a
8 solution to this issue. It's the phase where we had a
9 number of parties trying to better define the balance of
10 prescribing versus abuse and addiction. So -- and who would
11 really be proper in looking at, again, updates on evidence
12 of what really actually worked instead of the conservatism
13 of opioid prescribing which has been impactful to the
14 standard of care, and I think it resulted in that downward
15 curve. I know that from looking at this curve also in my
16 own experience.

17 **Q.** So we've mentioned a couple of times the 2015 CDC
18 guidelines. Those are at 02523. Those have been admitted
19 through Dr. Gupta.

20 If you could take a look at those, are those, in fact,
21 the 2016 CDC guidelines?

22 **A.** Those are the CDC guidelines from 2016.

23 **Q.** And did these guidelines make recommendations about how
24 doctors should limit the quantity of opioid medications they
25 prescribe to patients?

1 **A.** It talked about both quantity and dose.

2 **Q.** To your understanding, were these the first guidelines
3 from the federal government that told doctors they should
4 carefully reassess evidence of individual benefits and risks
5 when increasing dosage above daily thresholds?

6 **A.** I believe that it is.

7 **Q.** And were they the first federal guidelines that told
8 doctors treating acute pain that they could generally limit
9 prescriptions to a several-day supply, I think a three-day
10 supply?

11 **A.** I believe that it was.

12 **Q.** And I think you testified earlier that your committee
13 put together the SEMP guidelines partly in reaction to the
14 CDC guidelines coming out. Is that fair?

15 **A.** The CDC gave West Virginia a grant to create that
16 committee to -- you know, this is a guideline but it doesn't
17 really tell a primary care doctor what to do for example.

18 This was intended -- it says in this guideline for
19 primary care, although I feel like it applies to everyone
20 because it's good guidance. I think the CDC did a very good
21 job. Some people haven't liked this guidance, thought it
22 was too restricting. But I think it was very good.

23 And, so, the SEMP guidelines then were really created
24 to give a play book to doctors in West Virginia on, okay, if
25 you're going to do what the CDC says, how do you achieve

1 that?

2 So I think that was meant to be really a supplement to
3 CDC for our state particularly. And a few other states
4 adopted our SEMP guidelines as well. I know Arizona did.
5 There are pain societies and others.

6 **Q.** And, and I -- just for your benefit, if you need them,
7 Dr. Deer, the SEMP guidelines are at the very front of your
8 binder and they are 3036 and are admitted. They were also
9 released in 2016; right?

10 **A.** That's right. I believe this was -- March was the CDC
11 and I think the SEMP was October I believe.

12 **Q.** And did the CDC and SEMP guidelines encourage doctors
13 to caution basically now when prescribing opioids?

14 **A.** I think the CDC gave doctors a play book on amounts and
15 dosing. And I think SEMP gave doctors a play book on what
16 to do instead of opioids when possible.

17 **Q.** And to your knowledge, do doctors in West Virginia rely
18 on both the CDC guidelines from 2016 as well as the SEMP
19 guidelines from 2016?

20 **A.** I think it had a major impact on prescribing.

21 **Q.** And how do you know that?

22 **A.** Because, again, like I said earlier, back from '97 to
23 2015 or '16 I was receiving patients on more and more
24 controlled substances referred to me and my partners. And
25 we would spend time trying to find solutions.

1 And after these two documents came out, we started to
2 see a decline in that. The amounts were less. The doses
3 were less. So -- and people were sending patients earlier
4 to see us. They didn't wait five years after back surgery.
5 They waited three months after back surgery.

6 So I saw a shift in both the amount of drugs and the
7 time line of when people got sent to see us. But, again, it
8 was after these two, two major pieces of information were
9 given to physicians.

10 **Q.** And, so, is it your opinion, Dr. Deer, that the 2016
11 CDC guidelines as well as the SEMP guidelines had a role in
12 changing the standard of care in West Virginia?

13 **A.** I think they had major positive impacts in changing the
14 standard of care in West Virginia.

15 MS. MAINIGI: So let's come back to our chart,
16 Matt.

17 BY MS. MAINIGI:

18 **Q.** And, Dr. Deer, should we add the CDC guidance as
19 well as the SEMP guidelines to your chart?

20 **A.** Absolutely.

21 **Q.** Now, following on 2016 as we see distributions going
22 down in that time period, did the West Virginia legislature
23 pass any other legislation related to opioid prescribing?

24 **A.** In 2018 the West Virginia legislature passed new
25 legislation.

1 **Q.** And what was that called?

2 **A.** I don't remember the name exactly of the bill, but it
3 was a bill about really proper prescribing of opioids.

4 **Q.** And just -- I will ask you to take a look at 3054. And
5 does that refresh your recollection as to what it was
6 called?

7 **A.** It does, the Opioid Reduction Act. It seemed too
8 obvious to be the real name of the bill, but I think that
9 was it.

10 MS. MAINIGI: Your Honor, I ask the Court to take
11 judicial notice of the Opioid Reduction Act, 3054.

12 THE COURT: Any objection?

13 MR. FITZSIMMONS: No objection.

14 THE COURT: It's noticed and admitted.

15 BY MS. MAINIGI:

16 **Q.** Now, if you turn to Page 3 of this document, I
17 think it's 16-54-4. And under Subsection (e) --

18 MS. MAINIGI: If we could blow that up, Matt.

19 BY MS. MAINIGI:

20 **Q.** And that section is entitled "Opioid Prescription
21 Limitations." And can you describe to us what (e) says?

22 **A.** Yes. It really says -- it gives a guidance for
23 doctors. ER, four days of opioids for an injury; no more
24 than four days if you're in an outpatient setting with
25 Schedule II opioids, no more than four-day supply.

1 And if you decided that someone should be treated for
2 pain, no more than a three-day supply as an outpatient. And
3 then dentists and optometrists could only -- could not issue
4 more than a three-day supply after surgery.

5 And then lastly, as you've highlighted here, a
6 practitioner other than a dentist or optometrist could only
7 give a seven-day supply, the lowest effective dose which in
8 the medical judgment of practitioner would be best in the
9 course of treatment for his or her condition.

10 So it really limited when someone come to you
11 complaining of pain how much medication you could give
12 either emergently, acutely, or after a procedure, for
13 example.

14 **Q.** And was -- to your knowledge, was this type of
15 legislation being passed in other states as well?

16 **A.** It was.

17 **Q.** So let me ask you to look a bit further down on Page 3
18 at (g). Did that provision, Dr. Deer, limit doctors to
19 prescribing only a thirty-day supply of opioids with two
20 more thirty-day refills if that doctor checked the CSMP
21 database?

22 **A.** That's correct. It required them to give only that
23 first month. And then they could give two additional
24 prescriptions after that. And they had to check along that
25 time the data bank to see if they were getting other

1 prescriptions.

2 **Q.** And was this the first time the state had imposed an
3 objective limit on how many opioid medications doctors could
4 prescribe?

5 **A.** Yes, because there were doctors who would previously
6 write three months of prescriptions for someone in high
7 doses and say, "See me in three months," and send them home
8 with that. And that was not uncommon, particularly in
9 southern West Virginia.

10 So this said you can't do that. You have to reassess
11 the patient, make sure they still need the prescription. So
12 I think this was a very helpful piece of legislation.

13 **Q.** And if you turn to Page 5 under 16-54-5, subsequent
14 prescriptions and limitations, do you see that the act
15 required doctors to inform patients about alternatives to
16 opioid medications and the risks associated with opioid
17 medications before prescribing them?

18 **A.** Yes. I think both those were very important. The risk
19 had to be at least noted that this could be addictive and
20 could cause side effects. But also they had to tell them
21 other alternatives, whether it be injections, devices,
22 physical therapy. Before this act, they never had to
23 mention anything but medication to the patient.

24 **Q.** So to your understanding, what was the intended effect
25 of this legislation on inappropriate opioid prescribing?

1 **A.** I think the CDC was helpful, but it didn't go far
2 enough as far as some of the problems we've seen. And I
3 think this lent doctors some guidance on how to do a better
4 job of really prescribing more judiciously initially because
5 as I said earlier, once someone chronically has been on a
6 medication, it's very difficult to reduce it or limit it.

7 So this is looking at the initiation of opioid
8 therapies somewhat and I think that's where my advice has
9 been for some time.

10 MS. MAINIGI: Matt, if we could go back to the
11 chart.

12 BY MS. MAINIGI:

13 **Q.** Should we add the 2018 West Virginia Opioid
14 Reduction Act?

15 **A.** It is a major factor in changing the standard of care
16 in West Virginia in a positive light.

17 **Q.** So these recent laws from 2012 -- and guidelines from
18 2012, 2016 and 2018, have they together resulted in a change
19 of the standard of care in West Virginia?

20 **A.** I think the data shows there's no doubt about that.

21 **Q.** And did any of those requirements exist before 2011?

22 **A.** No. I think the '12 act was written based on what we
23 were seeing before '12. And there was no act before that
24 that limited prescribing or anything else to do with
25 opioids.

1 Q. In your opinion, Dr. Deer, do doctors in West Virginia
2 today have the information that they need to make good
3 decisions about prescribing opioids?

4 MR. FITZSIMMONS: Judge, I'm going to object to
5 him testifying globally as to all doctors. As to
6 anesthesiologists or people involved in his specialty, which
7 he's certainly recognized as a specialist in pain medicine,
8 I believe he can testify. But for him to get in here and
9 talk about what gynecologists, obstetricians, pulmonologists
10 and other doctors in the medical profession, I think it's
11 far in excess of his expertise.

12 MS. MAINIGI: Your Honor --

13 THE COURT: The question was in his opinion as an
14 expert do doctors in West Virginia today have the
15 information that they need to make good decisions.

16 I'm going to overrule the objection and allow him to
17 answer that. Now, the issues you raised I think would be
18 appropriate for cross-examination, but I'm going to overrule
19 the objection to that question.

20 MR. FITZSIMMONS: Your Honor, may I put one more
21 thing on the record? I apologize.

22 THE COURT: Yes, you may, absolutely.

23 MR. FITZSIMMONS: In West Virginia as an expert
24 you have to be an expert and qualify within the specialty
25 actually that you practice. And you have to practice so

1 much of that time.

2 He's already testified he's not a primary care
3 physician, doesn't practice in primary care. All of his
4 practice is referral care.

5 So he would not qualify -- could not qualify as an
6 expert in West Virginia to testify as an expert in anything
7 other than anesthesiology or pain management.

8 THE COURT: Well, your objection will be preserved
9 for the record, Mr. Fitzsimmons. But he is an expert in
10 pain management and I think this generally goes to that
11 subject. But your objection is shown on the record.

12 Go ahead, Ms. Mainigi.

13 MS. MAINIGI: Thank you, Your Honor.

14 BY MS. MAINIGI:

15 **Q.** Dr. Deer, are you aware whether there have, in
16 fact, been a decrease in prescriptions for opioid
17 medications in West Virginia since 2011?

18 **A.** Yes. There's been a major decrease in prescribing of
19 controlled substances, particularly Schedule IIs.

20 **Q.** I'm going to ask you to turn to 850, the last document
21 in the binder. Can you identify what this document is?

22 **A.** I was waiting for you to show it up on the screen.
23 It's a West Virginia Board of Pharmacy Controlled Substance
24 Annual Report from 2018 which I believe might be the last
25 year recommending that, right around that time.

1 Q. And are you familiar with this report?

2 A. I'm very familiar with it.

3 Q. Is this report made available publicly to your
4 knowledge?

5 A. I think that it is.

6 MS. MAINIGI: Matt, if we could put that up on the
7 screen.

8 THE WITNESS: There we go.

9 BY MS. MAINIGI:

10 Q. Now, is the purpose of this report to outline the
11 activities of the Board of Pharmacy in administering the
12 CSMP?

13 A. Yes.

14 MS. MAINIGI: Your Honor, I would like to move for
15 the admission of 00850.

16 THE COURT: Any objection?

17 MR. FITZSIMMONS: No objection, Judge.

18 THE COURT: It's admitted.

19 BY MS. MAINIGI:

20 Q. If you could turn to Page 4 of the document,
21 please. Now, what does in 2018 the West Virginia Board
22 of Pharmacy say has been the change in dispensing of
23 hydrocodone and oxycodone since 2011?

24 A. Want me to read that portion?

25 It says that the opioids, Schedule II, hydrocodone and

1 oxycodone, have seen the most significant drop in numbers
2 with a combined decrease of over 61 million doses since 2011
3 and 18 million dose increase last year alone going up to
4 2018. So that's in Figure 5.

5 **Q.** And, so, if we take a look at Figure 5 -- let's go to
6 that -- which I think is on the next page. And that's
7 entitled "West Virginia Opioid Drug Doses Dispensed."

8 So what does this chart show about the trend in
9 dispensing hydrocodone and oxycodone?

10 **A.** I think it shows what we've talked about from the 2018
11 law, 2016 CDC, and 2016 SEMP, that the opioid prescribing
12 for hydrocodone and oxycodone, the market has been reduced.

13 It also shows that buprenorphine has gone up some. And
14 that before was used only for abuse as a drug for addiction.
15 But now it's been approved for pain in low doses and it's
16 thought to be less addictive because it's an antagonist,
17 which for the Court means it actually has both pain
18 reduction and opioid abuse reduction properties.

19 This mimicks exactly -- if we go to 2011 to '18, this
20 mimmicks exactly what we've seen. In 2011 we probably
21 reached our peak of receiving maybe 50 to 100 patients a
22 month that came to see us on high-dose opioids which we'd
23 have to take over and try to manage.

24 And now in 2018 we're seeing very few people come to
25 see us on high-dose opioids at all, which means we're going

1 to have a better chance of helping them. And it's gotten
2 even less so I believe in the last year. We're seeing even
3 less and less.

4 So I think this mirrors what I've seen personally in
5 our practice as a referral for most of southern West
6 Virginia. It shows that those three things that we talked
7 about have been successful, I believe, in changing the
8 standard of care towards a more judicious approach to opioid
9 prescribing.

10 **Q.** And the three things we talked about, can you explain
11 what you mean by that?

12 **A.** Yeah. The three things we talked about was the 2018
13 legislation which we talked about a moment ago; the SEMP
14 guidelines which are the play book for West Virginia
15 doctors; and the CDC guidance which gave us dosing
16 recommendations.

17 **Q.** And what about the 2012 legislation?

18 **A.** The 2012 legislation helped us, I believe, to really
19 establish what a pain clinic was because there were people
20 calling themselves pain clinics who had no training, no
21 expertise, no ability to do multi-modal therapies where you
22 have physical therapy and other therapies available.

23 And I think it also gave some notice that you had to go
24 back and check the Board of Pharmacy records. It also
25 established the Board of Pharmacy committee which I think

1 really was -- in fact, some of the people that were
2 prescribing haphazardly were found to be noted in that
3 committee's findings.

4 **Q.** And let me come back to your practice which you said is
5 an exclusively referral practice; right?

6 **A.** Correct.

7 **Q.** And is it family physicians primarily that are
8 referring to you?

9 **A.** Well, so, if you look at our data from referral
10 sources, we get referrals from everyone, you know, from
11 surgeons who operate on someone's spine, from thoracic
12 surgeons who have taken out a tumor from your lung, from
13 urologists with prostate cancer, gynecologists with pelvic
14 pain.

15 But the vast majority of our patients come from the
16 family physician, probably 90 percent. Those other
17 specialties make up, each of them, a percent or two, maybe
18 80 percent family practice I would say.

19 I think we're talking about the non-cancer population.
20 The cancer population is a whole different bucket. Those
21 are mostly from the oncologists, but sometimes from
22 radiation oncologists, sometimes from family physicians.

23 **Q.** So from your practice, which is other physicians
24 referring to you, do you have a pretty good sense of the
25 prescribing patterns of other types of physicians in West

1 Virginia?

2 **A.** I think as you look at the report we've been talking
3 about, the 2018 report, Figure 3 shows the controlled
4 substances doses dispensed. That's a mirror image of what
5 I've seen because as we saw that peak on that graph in 2012,
6 that's when I saw my peak.

7 Everybody that came to me almost from southern West
8 Virginia was on 100 milligrams of morphine equivalents a day
9 or more. And we, we would then take that patient and try to
10 do a spinal cord pacemaker or an ablation, reduce their
11 doses.

12 And we were successful. But every time we got rid of
13 some of those opioid burdens, there was a new sieve of
14 people coming in who were on the same dosage. Right? So we
15 kept seeing it get refilled.

16 After 2015-'16 it started to decrease. After '18, the
17 legislation we talked about. Most people that come to see
18 me now are on no opioids or very little except for my cancer
19 patients.

20 The reason that's important -- I just published a new
21 study with the Mayo Clinic on combined patient population.
22 We showed our devices work better in lower dose with no
23 opioids. So our chances are better now than they were
24 before of helping you.

25 So I think we've seen a real shift and I've seen it

1 personally in my own prescribing habits because I take over
2 what I can.

3 **Q.** Okay. So just to summarize now what we've been talking
4 about for the last few hours, Dr. Deer, in your opinion, has
5 the standard of care for the prescription of opioids changed
6 over time?

7 **A.** It's been quite a journey and it's changed dramatically
8 over time in different directions.

9 **Q.** And has that changing standard of care affected the
10 rate at which doctors prescribe opioids in West Virginia
11 over time?

12 **A.** I think the data shows that it has. That's my personal
13 experience.

14 **Q.** And in your opinion, do physicians affect the standard
15 of care?

16 **A.** Well, physicians determine the standard of care, if you
17 will, because we, we hold each other accountable for what
18 we're doing and we learn from each other. Sometimes we
19 learn things that later prove to be untrue based on new
20 research and development.

21 So that's why the standard of care changes. I may have
22 an opinion in 1997 that in 2015 you see that was incorrect
23 looking backward. So it changes based on new information.
24 That's why research is so important and that's why, you
25 know, a big part of my practice is research and development.

1 **Q.** Did the DEA affect the standard of care?

2 **A.** I think it did. I think the local DEA people I know
3 are wonderful people and very good, but nationally the
4 policies that Ms. Tandy and others --

5 MR. FITZSIMMONS: Judge, I'm going to object to
6 him testifying about policies of the DEA.

7 THE COURT: Sustained.

8 MR. FITZSIMMONS: I don't think he's qualified.

9 BY MS. MAINIGI:

10 **Q.** Did the VA affect the standard of care?

11 **A.** Yes. The VA policies on fifth vital sign affected
12 standard of care.

13 **Q.** And did the Joint Commission affect the standard of
14 care?

15 **A.** Joint Commission definitely affected the standard of
16 care.

17 **Q.** And I think you've already answered this, but did West
18 Virginia's legislature affect the standard of care?

19 **A.** Legislation definitely affected the standard of care.

20 **Q.** And did West Virginia's Board of Medicine affect the
21 standard of care?

22 **A.** Board of Medicine certainly helps determine the
23 standard of care.

24 **Q.** In your opinion, based on your experience and your
25 understanding, did wholesale distributors have any affect on

1 the rate at which doctors in West Virginia prescribed
2 opioids?

3 MR. FITZSIMMONS: Judge, this is the third time, I
4 think, that I've objected. He's been designated not to
5 testify -- he doesn't know anything about distributors.

6 THE COURT: Well, you'll have to lay a basis for
7 it, Ms. Mainigi. I think the question is objectionable as
8 it stands.

9 MS. MAINIGI: Okay, Your Honor. I'll just
10 withdraw the question for now.

11 BY MS. MAINIGI:

12 **Q.** Dr. Deer, in terms of your own practice, explain to
13 us how your practice is a mirror on what's happened in
14 West Virginia.

15 **A.** Well, I believe that, you know, when we -- when you
16 take patients off the street because they requested seeing
17 you or you get a family doctor or you are a specialist, you
18 will get patients based on who's heard about your practice
19 or how you market or advertise your practice.

20 As a referral only practice, we actually receive
21 patients that, again, throughout the State of West Virginia
22 and they're sent to see us already undergoing certain
23 treatments.

24 As we talked about earlier, you know, 10 years ago
25 everyone was on high-dose opioids. Now we're seeing other

1 things being tried. So I think it goes to show you that
2 West Virginia, greatest state in America in my opinion -- I
3 know you're not from here -- we've made a good effort to
4 change things as a whole and we've evolved. Hopefully we'll
5 continue to evolve for the better and we'll continue to make
6 progress.

7 Q. Thank you, Dr. Deer.

8 MS. MAINIGI: I have no further questions, Your
9 Honor. I'd like to go ahead and mark the timeline as
10 Cardinal Demonstrative Number 2 and provide a copy to the
11 Court.

12 THE COURT: You may do so. And it's five till
13 12:00. Let's adjourn until 2:00 rather than start your
14 cross-examination, Mr. Fitzsimmons. Is that okay with you?

15 MR. FITZSIMMONS: That's good with me, Judge.

16 THE COURT: Okay.

17 We have to ask you to come back at 2:00, Dr. Deer.

18 THE WITNESS: Yes, sir. Thank you, sir.

19 THE COURT: We'll see everybody at 2:00.

20 MS. MAINIGI: Thank you, Your Honor.

21 (Recess taken at 11:55 a.m.)

22 THE COURT: If you'll resume the witness stand,
23 Dr. Deer.

24 THE WITNESS: Thank you, sir.

25 THE COURT: All right, sir. You may proceed.

1 MR. FITZSIMMONS: Thank you, Your Honor.

2 CROSS EXAMINATION

3 BY MR. FITZSIMMONS:

4 Q. Good afternoon to you. Dr. Deer, how are you?

5 A. Good, sir. How are you?

6 Q. I'm doing fine, thank you. We met for the first time
7 today, a little bit earlier this morning, and exchanged some
8 pleasantries at that time; is that right?

9 A. That's true.

10 Q. Okay. All right. So, you've been on the stand here
11 for awhile. I'm going to try to ask you some very direct
12 questions and, hopefully, get those answers from you, which
13 I know we will here today.

14 Do you agree that there is an opioid epidemic crisis in
15 this country right now?

16 A. Absolutely. It's been going on for awhile now.

17 Q. It's been going on for sometime, too; is that correct?

18 A. Yes, sir.

19 Q. At least before 2006; is that correct?

20 A. Yes, sir.

21 Q. And that crisis and that epidemic, can we interchange
22 those two words, crisis and epidemic?

23 A. I don't know.

24 Q. Have you done that?

25 A. I wouldn't argue that point. They're both pretty bad.

1 Either way, it's a bad thing.

2 **Q.** One of the things, I don't want to have word fights, or
3 games, or things like that.

4 **A.** Yes.

5 **Q.** So, can we agree that epidemic, crisis, that's what's
6 going on here in this country?

7 **A.** Again, I'm not a wordsmith. I don't disagree with you.
8 I'm not sure they're the same word, but yeah. I mean,
9 that's fine.

10 **Q.** Okay. All right. Do you agree that there's an
11 epidemic, a prescription opioid epidemic, that's existed in
12 West Virginia?

13 **A.** I think that's -- I think that's -- there's been a lot
14 of prescriptions in West Virginia. I'm not sure I would
15 call that an epidemic for the reasons we've talked about
16 today in the discussion. Certainly, it's changed, though,
17 recently in the last few years, which has been, I think,
18 very good, in my opinion.

19 **Q.** 2006, we certainly were in the opioid -- prescription
20 opioid epidemic here?

21 **A.** Well, again, not to be argumentative, but what I would
22 say is that based on what we talked about earlier today, I
23 think the standard of care evolved that way to a lot of
24 prescriptions being written and the majority -- and the vast
25 majority for legitimate reasons and, certainly, it's changed

1 now back to less prescribing. So, I don't know if that's --
2 I wouldn't call that an epidemic as much as a situation that
3 occurred.

4 **Q.** Doctor, I will repeat my question. In 2006, was there
5 a prescription opioid epidemic in this state?

6 MS. MAINIGI: Objection. Asked and answered, Your
7 Honor.

8 THE COURT: Overruled.

9 THE WITNESS: I'm not sure I would call that an
10 epidemic for the reasons I stated earlier about standard of
11 care. There were a lot of prescriptions written in West
12 Virginia, for sure, a high volume of prescriptions in 2006.
13 And that continued until about 2018, I believe, when the law
14 that we talked about earlier came into effect.

15 BY MR. FITZSIMMONS:

16 **Q.** Do you agree that there was a large volume of
17 prescription pills and opioid pills distributed into this
18 state back in the 2006 year?

19 MS. MAINIGI: Objection. Scope. Outside the
20 scope of this expert's expertise, Your Honor.

21 THE COURT: Overruled.

22 THE WITNESS: So, I would use the word prescribed
23 because that's what I'm familiar with and I assume, if you
24 prescribe a pill, someone has to distribute the pill. So,
25 there was a lot of pills prescribed in West Virginia. I

1 think, if that's the question, the answer is --

2 (Unintelligible cross-talk)

3 Yes, sir, I agree with that.

4 BY MR. FITZSIMMONS:

5 **Q.** And that volume, whether you use the word epidemic or
6 crisis, that volume was a cause, one of the causes of the
7 opioid crisis or epidemic at that time?

8 MS. MAINIGI: Objection. Calls for a legal
9 conclusion.

10 THE WITNESS: So, I think that --

11 THE COURT: Just a minute.

12 MR. FITZSIMMONS: Hold one second, Doctor. The
13 judge has to rule.

14 THE WITNESS: Oh, sorry.

15 MR. FITZSIMMONS: That's okay.

16 THE COURT: He's asking about the cause, not for a
17 legal conclusion.

18 You can answer the question.

19 THE WITNESS: Would you repeat the question, sir?
20 I'm sorry.

21 BY MR. FITZSIMMONS:

22 **Q.** Yeah. I'll try to, okay? Sometimes I miss a word or
23 two.

24 But the volume of the prescription opioids into the
25 state back in 2006 was a cause of the crisis or epidemic,

1 opioid epidemic or crisis that we talked about; is that
2 correct?

3 **A.** I think as we look backwards to what the standard of
4 care was back in 2006, it was more opioids prescribed then
5 than we would now recommend someone prescribe. So, I would
6 say, in retrospect, it was excessive.

7 **Q.** That's a yes?

8 **A.** I think that's a yes. I just want to make sure we're
9 on the same page with our question.

10 **Q.** All right. All right, good.

11 **A.** So, yeah.

12 **Q.** All right. And you are not an expert on all the
13 various type causes for this epidemic here, opioid
14 prescription epidemic in West Virginia; is that a correct
15 statement?

16 **A.** That's correct, sir.

17 **Q.** Right. And you've told us that both in your
18 deposition, your report, and in every writing that you've
19 had in this case; is that correct?

20 **A.** Yes, sir.

21 **Q.** All right. And we still have an opioid crisis today
22 that we're still fighting; is that correct?

23 **A.** I think it's evolved into non-prescribed drugs, from
24 what I've seen, like heroin and fentanyl and all the things
25 people use. So, but it's still a crisis nonetheless and

1 people still have problems in West Virginia with opioids.

2 Q. Heroin is an opioid, is it not?

3 A. Yes, sir.

4 Q. How about fentanyl?

5 A. Fentanyl is an opioid.

6 Q. Okay.

7 A. Yes, sir.

8 Q. So, opioids, we still have problems with opioids,
9 right?

10 A. Well, that was the answer I was giving you. I think
11 that it's changed over time, but it's still an opioid
12 problem in West Virginia.

13 Q. And so, we also know, Doctor, I think you do, that
14 around 2012, '14, in that time period approximately, it
15 looks like the opioid, prescription opioids, started to go
16 down on this Pill Mountain, we call it, that you see, that
17 big orange mountain here; is that right?

18 A. Yes, sir, that's correct.

19 Q. Okay. And that's when fentanyl and heroin started to
20 go upwards? Are you aware of that?

21 A. I'm not aware of that, but until -- I don't know that,
22 that fact. I haven't looked at that. Certainly, if you
23 have any -- anything you want me to look at, but I'm not
24 disagreeing with you. Just I don't -- I don't treat
25 addiction and I don't know much about -- I always defer to

1 my addiction experts around the area. So -- but I have no
2 reason to disagree with you.

3 **Q.** All right. So, you're a specialist in anesthesiology?

4 **A.** Well, I am board certified as an anesthesiologist, but
5 I haven't practiced. I haven't put anybody to sleep since
6 --

7 **Q.** Sir -- sir, so --

8 **A.** -- 1996. So, if you'd ask me to put you to sleep --

9 MS. MAINIGI: Your Honor, if the witness could be
10 allowed to finish the answer that he's been asked to give.

11 THE COURT: Well, yeah. He can explain his
12 answer, Mr. Fitzsimmons.

13 MR. FITZSIMMONS: I thought I did, Judge. I
14 thought I was being very polite, but I apologize if I
15 didn't.

16 THE WITNESS: Oh, I was just saying, I haven't
17 practiced anesthesiology really, haven't put anyone to sleep
18 since 1996. So, if I put you to sleep today, you would be
19 in grave danger probably because I would be outdated and not
20 know what I'm doing.

21 But I practiced a sub-specialty of anesthesia called,
22 you know, pain medicine since 1994, but in '96, only pain
23 medicine.

24 BY MR. FITZSIMMONS:

25 **Q.** Okay. So, you go into internal medicine, and you go

1 into anesthesiology, and now you're -- and you've been in
2 pain management basically?

3 **A.** Yes, sir.

4 **Q.** That's your thing?

5 **A.** Yes, sir.

6 **Q.** And you're board certified?

7 **A.** Yes, sir.

8 **Q.** All right. You are not a primary care physician; is
9 that a true statement?

10 **A.** That's a true statement.

11 **Q.** And a primary care physician is one that treats primary
12 illnesses and then typically refers more serious-type cases
13 out if they can't handle it, like a family practice medicine
14 person or a general internal medicine person; is that
15 correct?

16 **A.** I think that's true, sir. Yes, sir.

17 **Q.** But the entire medical community prescribes pills,
18 including opioids, if they're registered and licensed to do
19 that, right?

20 **A.** That's right.

21 **Q.** Obstetricians, gynecologists, pulmonologists,
22 orthopedics, surgeons, general surgeons; is that right?

23 **A.** Everything you said is true, yes.

24 **Q.** Okay. All right. So, and you also -- from your
25 experience with dealing with pain management, you realize

1 and I think you've acknowledged that prescription opioids in
2 this state, in this country, are principally -- are
3 principally prescribed by primary care physicians; is that a
4 true statement?

5 **A.** That would be a true statement.

6 **Q.** Over 65 percent of the primary prescriptions in this
7 state come from primary care physicians; is that correct?

8 **A.** Yes, sir, I believe that's correct.

9 **Q.** One of which is not you?

10 **A.** That is correct, also, sir.

11 **Q.** Okay. So, I think I heard you give a general standard
12 of care and I wanted to -- I did want to share that with you
13 a little bit and talk -- discussion about standard of care.
14 Whose standard of care are you talking about? Are we
15 talking about lawyers? Are we talking about pharmacists?
16 Are we talking about distributors? Are we talking about
17 obstetricians? Pain management? People -- who -- who are
18 you expressing -- were you expressing the standard of care
19 opinion on when you were asking --

20 THE COURT: Just a minute. Ms. Mainigi?

21 MS. MAINIGI: Sorry, Your Honor. I was just
22 waiting for the question to finish. Objection to the form
23 of the question, Your Honor.

24 THE COURT: Well, overruled. The answer [sic] is
25 whose standard of care are you talking about. Can you

1 answer that question, please?

2 THE WITNESS: Yes, sir, I believe I can. So, it
3 will take me a moment to answer it.

4 BY MR. FITZSIMMONS:

5 **Q.** Yes. Do you want me to ask it?

6 **A.** No. I can answer it. It's going to take me a moment.
7 So, standard of care would be more reasonable a doctor would
8 do in a situation based on the standard set for doctors by
9 doctors, in my opinion, overall over time influenced by
10 other outside variables that we've talked about today.

11 And, for example, a standard of care of postoperative
12 wound care may be the same for a vascular surgeon, or a
13 pulmonologist, or a general surgeon because it's wound care.
14 So, standard of care in opioids, there are parts of that
15 that apply to all physicians who prescribe an opioid,
16 whether they be an anesthesiologist or a primary care
17 specialist.

18 So, there are -- standard of care is set based on what
19 you're doing and then it applies back to who you are and
20 what your training is. So, there's some overlap there in
21 standard of care based on your specialty and what you're
22 doing and they can be unique.

23 For example, how to do a pap smear is very unique to a
24 gynecologist. And, you know, how to -- how to use
25 antibodies preoperatively is the same for all surgeons. So,

1 if you see what I'm saying, there's overlaps.

2 So, standard of care is set by the medical community
3 for the medical community and often is specialty related,
4 but sometimes crosses specialty.

5 **Q.** So, to break it down, you were testifying about
6 standard of care of doctors?

7 **A.** Correct.

8 **Q.** But only the overlapping aspects of prescription
9 opioids among those professions, those specialties?

10 **A.** I'm not sure I understand your question. I'm sorry.

11 **Q.** You used overlapping. I'm trying to get an idea. You
12 aren't an obstetrician? You've never practiced obstetrics?

13 **A.** Well, if an obstetrician today gave -- I'll give you a
14 -- can I give you an example?

15 **Q.** Could you answer the question?

16 **A.** I'm going to answer your question with an example, if I
17 could.

18 **Q.** You are not an obstetrician?

19 **A.** Or no. I didn't answer that part of the question. You
20 asked another question first. Sorry. No, I'm not an
21 obstetrician for sure.

22 **Q.** All right. So, do you know when obstetricians
23 prescribe opioid pills?

24 **A.** I do often because they refer those patients to me for
25 chronic pelvic pain, for example. So, they may have been on

1 an opioid for a long time, but now, we're doing new
2 procedures for that issue around the sacral nerve root. So,
3 we often get that patient sent to us.

4 So, I know when they prescribe opioids. You may -- I
5 may not know why they chose to choose to start the opioid.
6 That may be a different issue altogether. That's what I
7 meant by overlapping in these issues. They're a little more
8 complicated than just that.

9 **Q.** Have you ever written standards of care for opioid
10 prescriptions?

11 **A.** Is there a written standard of care?

12 **Q.** Any written document, uh-huh, that you put in writing?

13 **A.** There are written guidelines for opioid prescribing.
14 That can be part of the standard of care.

15 **Q.** That's what you were talking this morning?

16 **A.** Earlier, I said that --

17 (Cross-talk)

18 THE WITNESS: I didn't mean to interrupt you. I'm
19 sorry. Did I interrupt you?

20 I was saying earlier that they can be written or they
21 can be -- community determines it over time, you know,
22 different means, speeches, and I think this includes both.

23 BY MR. FITZSIMMONS:

24 **Q.** So, your written guidelines in 2012, those are standard
25 of care, I think you said; is that right?

1 **A.** No. I don't think I said that.

2 **Q.** Are they?

3 **A.** Which guidelines are you talking about in '12?

4 **Q.** A set of guidelines that you were one of the chief --

5 **A.** You mean the SEMP guidelines in 2015, '16 --

6 (Cross-talk)

7 **Q.** You were talking about the ASIIPP guidelines, which
8 actually made this chart. You got a little flag today for
9 that.

10 **A.** Yeah. I don't think they're standard of care. I think
11 they're part of what determines standard of care in the
12 guideline because a guideline is only as good -- they're a
13 consensus, if you will. So, they're written by multiple
14 people and everyone agrees.

15 It's almost like when you have a -- you know, a bill
16 that people debate on what's appropriate to put in a bill
17 with Congress. We debate on what's appropriate. There's
18 not a hundred -- you have to have 80 percent of the people
19 agree to any section of a guideline to make it a consensus
20 guideline. Otherwise, it would be a unanimous guideline.
21 That's why you call it a consensus guideline. So, I
22 wouldn't say they're standard of care, but they help make
23 the standard of care.

24 **Q.** Are you finished with your answer?

25 **A.** Yes, sir, I am.

1 **Q.** Okay. So, this approximately hundred-page two-part
2 guidelines that you and 35 other physicians put together,
3 call them guidelines, you're disavowing that they are
4 standard of care for the prescribing of opioids?

5 **A.** Many guidelines say in them --

6 **Q.** Is that a true statement?

7 MS. MAINIGI: Objection.

8 COURT REPORTER: I'm sorry --

9 MS. MAINIGI: Misstates the witness's testimony.

10 THE WITNESS: I was trying to answer.

11 THE COURT: Just a minute. Well, I'm not sure
12 he's explained his answer.

13 Go ahead. You can -- you can continue.

14 THE WITNESS: Thank you, sir.

15 Could you repeat the question?

16 BY MR. FITZSIMMONS:

17 **Q.** Is that a true statement?

18 **A.** I lost the question. Sorry.

19 **Q.** Are you disavowing that the guidelines that you and
20 30-some other physicians put together in 2012 under a group
21 called ASIPP, American Society of Interventional Pain
22 Physicians Guidelines for Responsible Opiate Prescribing and
23 Chronic Non-Cancer Pain, Part 1, Evidence Assessment and
24 Part 2, Evidence Assessment is the standard of care?

25 **A.** So, I'd like to explain my answer, if I could.

1 Q. Could you the answer the question first?

2 A. Well, I don't think it's a yes or no. It's a different
3 answer than that.

4 (Cross-talk)

5 Q. The answer is no? Okay.

6 A. I'd like to --

7 MS. MAINIGI: Your Honor, if he could just be
8 allowed to answer the question.

9 (Unintelligible cross-talk)

10 MR. FITZSIMMONS: I'm sorry.

11 THE COURT: Yeah. Let him finish, Mr.
12 Fitzsimmons.

13 MR. FITZSIMMONS: Yeah. I couldn't -- I can't
14 hear his answer.

15 Could you pull the mic a little closer to you if --

16 THE WITNESS: Sure. So, let me explain my answer,
17 if I could.

18 So, most guidelines that I've written, including all
19 the device guidelines that I've read, say this is not meant
20 to be by itself a standard of care. So, guidelines usually
21 are not the standard of care by itself.

22 So, we -- I don't think we ever said it was a standard
23 of care and I would be surprised if that document said it
24 was the standard of care. It's one of the factors that goes
25 into standard of care.

1 So, I'm not avowing the standard of care or disavowing
2 it. Guidelines, there's also something in '17, I think an
3 update of that same paper. They are what's going on at the
4 moment, but many guidelines, by the time they go through the
5 journal process --

6 COURT REPORTER: I'm sorry. Can you slow down for
7 me, please?

8 THE WITNESS: I'm sorry.

9 COURT REPORTER: Thank you.

10 THE WITNESS: Many guidelines, by the time they go
11 through the journal process need to be updated almost
12 immediately by the time they're written. So, I don't think
13 guidelines have ever been the standard of care and I don't
14 think I've ever said that. But they contribute to the
15 standard of care as one factor we determine to look at.

16 BY MR. FITZSIMMONS:

17 **Q.** So, the 2017 one that also got one of the flags is not
18 a standard of care?

19 **A.** It's a determining factor of the standard of care, but
20 not the standard of care.

21 **Q.** Not the standard of care, right? 2012, those ones also
22 for ASIPP were not standard of care?

23 **A.** By itself are not standard of care.

24 **Q.** In 2006, when you wrote the paper on the guidelines,
25 were not standard of care; is that true?

1 **A.** By themselves, they're not standard of care.

2 **Q.** And so, let me ask you, you have all these writings on
3 guidelines. Have you ever put in writing the standard of
4 care for opioid prescriptions that we all can read?

5 **A.** I don't think that there is a paper that puts that in
6 direct writing because of the evolution of it but,
7 certainly, if you have something you would like me to look
8 at, I would be happy to.

9 **Q.** Thank you, Doctor.

10 All right. Let's talk about -- first of all, you know
11 that you're here testifying in a case brought by Cabell
12 County and Huntington as the plaintiffs; is that correct?

13 **A.** Yes, sir.

14 **Q.** All right. And it's against -- this portion of the
15 case is against three distributors, you now know, one of
16 which hired you? I think McKesson hired you?

17 **A.** Cardinal.

18 **Q.** Or, I'm sorry, Cardinal.

19 (Cross-talk

20 **Q.** Cardinal hired you? That's correct. All right. And
21 they're the only ones that hired you as an expert in this
22 case; is that true?

23 **A.** I believe that to be true, yes, sir.

24 **Q.** Okay. All right. And you understood it was about the
25 opioid crisis generally and your experiences, I guess?

1 **A.** I was asked to look at how prescribing had changed
2 among physicians from the beginning of my career until what
3 I hope is not the end yet. I hope I have a few years left.
4 We'll see.

5 **Q.** Okay. Hopefully, you do, Doctor.

6 All right. So, you were supplied information -- or did
7 you harvest and dig up all the documents, just go out and do
8 that yourself, or have you had assistance with attorneys
9 providing you with documents and a lot of those flagged
10 items and things like that for you to look at?

11 **A.** So, there are things that I think are important in my
12 own mind, like some of the legislation we've discussed
13 today, CDC guidelines, SEMP guidelines. And there are other
14 documents that I was provided, too, in our discussion that
15 the Cardinal company thought might be helpful to my
16 evaluation.

17 **Q.** All right. Anybody else supply you with information?

18 **A.** Not that I know of, sir.

19 **Q.** No? Okay.

20 All right. And when you met, did you meet only with
21 Cardinal Health and, obviously, I don't want to -- well, I
22 do want to know what you -- so, I'm not going to ask you
23 what was said and you --

24 **A.** I think I only met with Cardinal Health --

25 **Q.** Just Cardinal Health --

1 (Cross-talk)

2 **Q.** Counsel --

3 **A.** Yes, sir.

4 COURT REPORTER: I'm sorry. I'm having a hard
5 time with the cross-talk.

6 I got part of your answer. I think I only met with
7 Cardinal --

8 THE WITNESS: I think that to be true, yeah. I'll
9 -- I'll -- I tell you what, I'll pause. So, sorry if I'm
10 talking too fast. I get that way after a few coffees at
11 lunch. I apologize.

12 MR. FITZSIMMONS: All right. Are we caught up?

13 COURT REPORTER: Go ahead. I'll try.

14 MR. FITZSIMMONS: All right. We'll try. All
15 right.

16 BY MR. FITZSIMMONS:

17 **Q.** Let's talk about what you didn't do and what you didn't
18 review, okay, in this case.

19 **A.** Yes, sir.

20 **Q.** All right. So, Cabell County is the plaintiff in this
21 case, together with the City of Huntington. All right? So,
22 did you ever obtain the number of prescribed opioids from
23 Cardinal Health that were distributed into Cabell County?
24 Did you have that number over this 20 -- let's say 20-year
25 period. Let's take it from '96 to 2021. That makes it

1 25 years.

2 **A.** I don't believe so. Certainly, they gave me a lot of
3 information. If it were there, I don't recall it.

4 **Q.** My question is, do you believe that you received it?
5 If it's no, just --

6 **A.** I don't -- I don't believe. I'm under oath. I want to
7 make sure I don't mislead, but I don't think I ever received
8 that and I don't recall receiving it.

9 **Q.** Did you ever receive any data on the number of
10 pharmacies in Cabell County or Huntington?

11 **A.** I do not recall ever receiving that information.

12 **Q.** Did you ever receive any information as to the doctors
13 that were there that were actually had -- were registrants
14 that had the ability to prescribe opioid pills?

15 **A.** No, sir, I did not.

16 **Q.** Didn't have any of that? Did you have any data as to
17 the volume of pills, the actual amount that was distributed
18 into this particular county for any specific year during the
19 last 25 years?

20 **A.** In Cabell County?

21 **Q.** Yes. Yeah. I'm only going to ask about Cabell --
22 (Cross-talk)

23 THE WITNESS: No, sir, I do not.

24 BY MR. FITZSIMMONS:

25 **Q.** Or Huntington?

1 **A.** No, sir.

2 **Q.** Do you know how many physicians were indicted or busted
3 for some type of pill pushing in Cabell County during the
4 last 25 years?

5 **A.** I do not.

6 **Q.** Do you know of any?

7 **A.** You know, I think Dr. Fisher was in that county, I
8 believe. I remember when he got indicted and --

9 **Q.** You heard something about --

10 **A.** -- I think he got convicted. No. I think one of my
11 junior partners was testifying against him before the Board
12 of Medicine.

13 **Q.** Well, we're interested -- I'm interested in what you
14 know.

15 **A.** I know he got --

16 **Q.** Do you have any knowledge, any specific facts about
17 this Dr. Fisher as to what he did or didn't do or she did?

18 **A.** No, other than a newspaper reporting or a television
19 reporting that he was indicted and convicted of a crime
20 related to a relationship -- or the person was prescribing
21 without medical cause or something.

22 **Q.** So, your answer is no, you have no personal knowledge?

23 **A.** That's true. That's true.

24 **Q.** True? All right. So, do you have any knowledge as to
25 how many addicts were in -- drug addicts were in Cabell

1 County in 1996, 2001, 2010?

2 **A.** I assume you're talking about people who had addiction
3 treatment?

4 **Q.** People that formally could be diagnosed as an addict,
5 addiction?

6 **A.** So, they've been diagnosed by someone?

7 **Q.** By someone, yes.

8 **A.** Okay. No. I don't have a clue.

9 **Q.** Did you ever try to check to find out that?

10 **A.** That's not part of what I was looking at. It was
11 addiction -- I'm not an addictionologist, nor do I look at
12 addiction.

13 **Q.** Okay. Did you ever ask the people that hired you for
14 information concerning the prescriptions and data that they
15 had for all the pills for each of the years over the last,
16 let's say, 10, 15 years? Did you ask them can we see your
17 data and how much you distributed to Cabell County before I
18 go before this Court and give opinions?

19 **A.** Specific to Cabell County?

20 **Q.** I think that's been my last 20 questions.

21 (Cross-talk)

22 **A.** I just wanted to make sure. No, I didn't -- I didn't
23 look at that data, as far as I know.

24 **Q.** Did you ask for it?

25 **A.** Well, I wasn't looking at the issues of Cabell County

1 addiction rates. I was looking at the overall standard of
2 care of prescribing in West Virginia.

3 **Q.** Did you ever ask for any information about overdoses as
4 to prescription opioids in Huntington or Cabell County? Did
5 you ever ask to see those or have you ever seen any
6 information on that?

7 **A.** So, that was a long question. So, the last part of
8 your question --

9 **Q.** I can break it down.

10 **A.** No, no. The last part of your question is did I ever
11 see any of that. During our committee we talked about
12 earlier, if there was a death in Cabell County, that would
13 have been reviewed by our committee from 2012 to '18. I
14 don't recall that specifically, though, and I didn't ask for
15 specific data for this case. So, I hope that answered your
16 question.

17 **Q.** So, any of the -- there's what's called related harms
18 conditions that arise from addiction, that are more
19 prevalent because of the addiction, like HIV, Hepatitis B,
20 C, endocarditis. Are you familiar with that?

21 **A.** No, sir. I don't know anything about that.

22 **Q.** You wouldn't even know that, what I just stated
23 medically, whether that's true or not; is that right?

24 **A.** Well, I think --

25 (Cross-talk)

1 Q. Is that true? You don't know?

2 A. I'm sorry. The last part of your question, can you
3 repeat?

4 Q. The last part, is that true? You don't even know --

5 A. No, before that. I'm sorry.

6 Q. Before --

7 COURT REPORTER: I'm sorry --

8 MR. FITZSIMMONS: Yeah. I thought the witness
9 jumped in, but let me -- let me --

10 BY MR. FITZSIMMONS:

11 Q. I'll give you a signal and you can answer.

12 A. Okay, thank you.

13 Q. All right. So, you don't even know if Hepatitis B,
14 Hepatitis C, HIV, endocarditis, or any of these other
15 diseases or conditions, are related to a person that is an
16 addict?

17 A. Well --

18 Q. Is that a true statement?

19 MS. MAINIGI: Your Honor, objection. This is
20 completely outside the scope of Mr. --

21 (Cross-talk)

22 THE COURT: I'm sorry. This is way beyond the
23 scope of his direct, isn't it, Mr. Fitzsimmons?

24 MR. FITZSIMMONS: Well, Judge --

25 THE COURT: I realize that a wide latitude needs

1 to be allowed on cross --

2 MR. FITZSIMMONS: Well, Your Honor, I --

3 THE COURT: But this is pretty far afield.

4 MR. FITZSIMMONS: It has to do with his not --
5 look, he's giving an opinion on standard of care for the
6 entire medical world of all these different specialties and
7 we've allowed him to do that and we've objected. And now
8 he's being challenged, being tested, as to his knowledge
9 because of -- because this is very -- opioids is the essence
10 of this case, the prescription opioid use. And as to his
11 opinions in Cabell County, it shows one of the questions
12 Your Honor had asked several times, and I was watching on
13 the monitor, Judge, back in those days, back in the early
14 weeks. You were interested in Cabell County.

15 So, this is a problem in Cabell County and his lack or
16 knowledge about addicts and what goes on is very important
17 as to his opinions. He's given an opinion that you're going
18 to have to apply to Cabell County and what he keeps
19 testifying, that's -- this is what's going on in Cabell
20 County and Dr. Deer, who's very qualified --

21 THE COURT: What's it got to do with the changing
22 standard of care? And that's -- that's all he testified
23 about, wasn't it, Ms. Mainigi?

24 MS. MAINIGI: That's exactly right, Your Honor.
25 That's all his report covers. They've had notice of that

1 for a long time and I -- I realize this may be a technique
2 of Mr. Fitzsimmons to cover all the things that have -- that
3 he didn't look at. And I do believe Your Honor has allowed
4 wide latitude on this, but this is just improper questioning
5 given the scope of his testimony, as well as his report.

6 MR. FITZSIMMONS: Judge, I'll move on from that
7 question.

8 THE COURT: I think it's outside the scope. I
9 will sustain --

10 (Cross-talk)

11 MR. FITZSIMMONS: I think it goes to his
12 credibility --

13 COURT REPORTER: I'm sorry. Did you say sustain
14 it --

15 MR. FITZSIMMONS: -- on the standard of care on
16 this -- in this particular case.

17 BY MR. FITZSIMMONS:

18 **Q.** So, you're testifying as to Cabell County. How many
19 hospitals are are in Cabell County?

20 **A.** So, Cabell County is in West Virginia. I'm testifying
21 to standard of care in West Virginia for prescribing. I
22 didn't specifically look at Cabell County as a whole. St.
23 Mary's and Cabell-Huntington just merged. I believe they're
24 one hospital now. That's the main hospital.

25 Across the river in Ashland are two other hospitals, I

1 do believe. Our Lady of Bellefonte went bankrupt, though,
2 so I think they are now owned by King's Daughters. And I
3 think there are some surgery centers there, but the two main
4 hospitals are Cabell-Huntington and St. Mary's.

5 There's also a VA there run by the Veterans
6 Administration, which is part of Marshall Medical School, I
7 do believe.

8 **Q.** Okay. So, there's two hospitals and a VA?

9 **A.** Well, I told you I didn't specifically --

10 **Q.** Two or one --

11 **A.** I didn't look specifically at Cabell County, but that's
12 the -- that's what I'm familiar with.

13 **Q.** Well, whether there's two or one, are you -- do you
14 have privileges in Cabell County hospitals?

15 **A.** No, not currently.

16 **Q.** How long has it been since you were privileged over
17 there?

18 **A.** I think about 20 years ago. They actually asked me to
19 do some very specific things at St. Mary's. I think I
20 briefly held privileges there back in the late 90s, but that
21 was it.

22 **Q.** You gave an opinion that -- I think I wrote it down.
23 It was somewhere a little bit after 11:00 this morning. You
24 gave an opinion that most of the doctors, I think we were
25 talking about in the country, comply with the standard of

1 care that you had testified about, whatever that standard
2 was. Did I hear that correctly? My hearing is not very
3 good sometimes.

4 **A.** In the country? So, certainly, I think most prescribed
5 drugs follow that pattern, as you see around the country and
6 West Virginia. That became a standard as those phases
7 happened. I think the majority did, the vast majority.

8 **Q.** So, is that a yes?

9 **A.** I think that would be a yes.

10 **Q.** And so, most is not all; am I correct?

11 **A.** I think that's correct, sir. Yes, sir.

12 **Q.** So, all those other persons then are violating the
13 standard of care? You're familiar with that term, violation
14 of standard of care in malpractice cases and things like
15 that, right?

16 MS. MAINIGI: Objection. Form. The question
17 doesn't make any sense, Your Honor.

18 THE COURT: Overruled.

19 If you understand the question, Dr. Deer, you can
20 answer it.

21 THE WITNESS: I think I understand it, Your Honor,
22 but I'll try.

23 If you're outside the standard of care, you're
24 violating the standard of care, yes, sir.

25 BY MR. FITZSIMMONS:

1 Q. That's another yes, right?

2 A. I believe that would be a yes. I just like to quantify
3 myself to make sure I understand your question and my
4 answers. So, I have to say them. So --

5 Q. Okay. I'm trying to -- I'm actually trying to get very
6 clear questions to you so there's no misunderstanding.

7 A. Yes, sir.

8 Q. All right. So, people that don't -- that don't follow
9 the standard of care, that violate the standard of care,
10 many of those people are diverting pills, are they not?

11 A. So, I think that's two separate -- with all due
12 respect, I think you're asking me a question that doesn't
13 match. The physician outside the standard of care is not
14 diverting pills, but their improper prescribing could cause
15 diversion by someone else. So, it's a different answer than
16 what you asked.

17 Q. Let me change the question. If you insert the word
18 results, the people who violate the standard of care results
19 in some diversion?

20 A. If you're --

21 Q. If --

22 MS. MAINIGI: Objection, Your Honor. All I would
23 ask is, if Mr. Fitzsimmons could ask his question and not
24 keep layering onto his question and let the witness answer.
25 I'm sure the court reporter continues to have a difficult

1 time.

2 Again, I am sure he's not trying to confuse the witness
3 at all or put words in his mouth, but I'd really appreciate
4 it if he -- if Mr. Fitzsimmons could just ask the question
5 and then let the witness answer.

6 THE COURT: Can you slow down a little bit, Mr.
7 Fitzsimmons?

8 MR. FITZSIMMONS: Yes, Your Honor. Try to take --
9 I'm actually going pretty slow for normal, for most times.

10 BY MR. FITZSIMMONS:

11 **Q.** All right. Dr. Deer, so the physician, when there's a
12 violation of the standard of care, that can result in a
13 diversion; is that correct?

14 **A.** I believe the answer to that would be yes.

15 **Q.** Okay. Thank you. And you agree that there are lot of
16 bad prescribers; is that true?

17 **A.** You have to quantify what a lot is. I think the ones
18 that I have seen that, again, in my work reviewing charts
19 for different parties and bad physicians, you know, they
20 seem to stick out like a sore thumb usually. And so, I
21 don't know if it's a lot or the ones that we notice are
22 quite dangerous to the community.

23 **Q.** All right. So, in response to a question by Attorney
24 Metz -- or, no, that was Ms. Gaffney in your deposition. Do
25 you recall your deposition?

1 **A.** I do recall Ms. Gaffney from Seattle, yes, sir, I do.

2 **Q.** Do you recall having your deposition taken under oath
3 September 21st, 2020?

4 **A.** I do.

5 **Q.** And there had been a question asked --

6 MS. MAINIGI: Objection, Your Honor. I don't
7 think this is the proper way to impeach.

8 THE COURT: Well, are you --

9 MS. MAINIGI: I don't know what he's doing.

10 THE COURT: Is this a prior inconsistent
11 statement, Mr. Fitzsimmons?

12 MR. FITZSIMMONS: It will be when -- yes, but I'm
13 trying to lay that foundation first.

14 THE COURT: Okay, go ahead.

15 MR. FITZSIMMONS: It's -- no, it's not necessarily
16 an inconsistent statement. It's his answer.

17 MS. MAINIGI: Oh, well, Your Honor, that's
18 improper. He can impeach with a prior inconsistent
19 statement.

20 THE COURT: If it's not inconsistent, you can't
21 use it, Mr. Fitzsimmons.

22 MR. FITZSIMMONS: Okay. So, it's inconsistent
23 then because he said he didn't know what a lot meant.

24 THE WITNESS: I don't know what a lot means in
25 context.

1 MS. MAINIGI: But, Your Honor -- objection, Your
2 Honor. He just told the Court that it's not inconsistent.

3 MR. FITZSIMMONS: No, I said that --
4 (unintelligible)

5 COURT REPORTER: I'm sorry. I can't hear that.

6 THE COURT: Don't argue with each other. I'm
7 trying to figure this out. Is it inconsistent or not?

8 MR. FITZSIMMONS: It is inconsistent with his
9 answer, yes.

10 THE COURT: Well, then I will let you use it and
11 then we'll find out if it is or not, Ms. Mainigi.

12 BY MR. FITZSIMMONS:

13 Q. Do you recall in response to --

14 MR. FITZSIMMONS: This is -- put it up on the --
15 we have 130, starting Line 5, if we have to go back to the
16 question.

17 MS. MAINIGI: Could we get a page cite, please,
18 Your Honor?

19 MR. FITZSIMMONS: Yes. 130, Page 5. 130, Line 5.

20 MS. MAINIGI: Your Honor, my objection is that the
21 question that was posed that reflects the answer, I would
22 ask, first of all, Mr. Fitzsimmons to bring the answer off
23 the screen until this issue is resolved.

24 MR. FITZSIMMONS: Okay. Take that off, please.

25 And, Judge, I'll withdraw the question.

1 MS. MAINIGI: Thank you.

2 THE COURT: Well, what was the question you asked
3 him that you think his answer was inconsistent with what
4 you're going to do here?

5 MR. FITZSIMMONS: Yeah. I'm going to withdraw the
6 question and I'll ask another. I'm going to ask a question.

7 THE COURT: Okay. All right.

8 BY MR. FITZSIMMONS:

9 Q. Okay. All right. So, do you agree that there was a
10 lot of bad behavior by prescribers prescribing prescription
11 opioids in West Virginia?

12 MS. MAINIGI: Objection to form. Bad behavior? I
13 don't know what that means.

14 THE COURT: Overruled. He can answer that one.

15 THE WITNESS: I think there were some doctors who
16 prescribed inappropriately.

17 THE COURT: You understand bad behavior to be
18 inappropriate --

19 THE WITNESS: Well, I would think that would mean
20 inappropriate prescribing, is what it referred to.

21 BY MR. FITZSIMMONS:

22 Q. Was that a lot?

23 A. Well, again, I know you were going back to my
24 deposition where it says a lot. But, certainly, there is a
25 lot of doctors who mis-prescribe, but if you look at the

1 percentage of doctors, it's pretty low, but we do notice
2 that -- and one is too many in West Virginia, in my opinion,
3 and there were a lot more than one for sure.

4 MR. FITZSIMMONS: Gina, could you put 130, Line 5,
5 start with Line 5 all the way through?

6 MS. MAINIGI: Objection, Your Honor. I'm taking a
7 look at where I think Mr. Fitzsimmons is in the deposition
8 and I object --

9 MR. FITZSIMMONS: So, I was just --

10 MS. MAINIGI: Excuse me?

11 So, Your Honor, this is not a prior inconsistent
12 statement.

13 THE COURT: Overruled. Let's see where he goes
14 with this.

15 MS. MAINIGI: I would just ask, Your Honor, that
16 he not put it on the screen.

17 THE COURT: Oh, okay.

18 MS. MAINIGI: And that he ask the question and get
19 the answer.

20 THE COURT: Ask the question and then put it on
21 the screen.

22 MR. FITZSIMMONS: I'm sorry, Your Honor.

23 THE COURT: I think she's right. Don't put it on
24 the screen until you have asked him the question and then --

25 BY MR. FITZSIMMONS:

1 **Q.** Do you recall, Doctor, testifying that you knew there
2 was a lot of bad behavior by prescribers and there were some
3 good behavior by prescribers who didn't know any better in
4 retrospect?

5 MS. MAINIGI: Objection, Your Honor. That is not
6 the question that was asked of Dr. Deer at his deposition.
7 The proper way to impeach or to use a prior inconsistent
8 statement is to actually ask the question that was
9 previously asked, not try to summarize the answer that was
10 provided.

11 THE COURT: Well, that's right, Mr. Fitzsimmons.
12 What specific question --

13 MR. FITZSIMMONS: Judge, I --

14 THE COURT: Well --

15 MS. MAINIGI: Your Honor, if I may, the question
16 that was asked was, as a West Virginia Doctor, can you
17 describe the impact that the shipment -- this enormous
18 amount of pills has had on communities in West Virginia.
19 That was the question that was asked at the deposition.

20 THE COURT: And how did he answer it here? Did he
21 answer that question here?

22 MS. MAINIGI: Well, Your Honor, I would object to
23 the question. I mean, obviously, it was asked at the
24 deposition, but I would object to the question because it's
25 outside the scope.

1 THE COURT: Well, I'm going to let him go to the
2 deposition because I don't know what happened at the
3 deposition until I see it.

4 So, go ahead and finish it, Mr. Fitzsimmons.

5 MS. MAINIGI: Well, could the witness -- Your
6 Honor, could the witness be allowed to answer the question
7 if that's the question?

8 THE COURT: I thought he did answer it.

9 MS. MAINIGI: This question has not been posed to
10 the witness, Your Honor, so if -- the question that was
11 actually asked at the deposition, if that could actually be
12 posed to the witness, that would be the proper form for any
13 inconsistent statement.

14 THE COURT: Well, I think that's right, Mr.
15 Fitzsimmons.

16 MR. FITZSIMMONS: Judge, he's answered as to the
17 word a lot. He said he didn't know what that meant and I
18 asked him whether he had used it in describing it, which is
19 why the deposition testimony -- his words were being used to
20 impeach him as to what he doesn't know.

21 THE COURT: Well --

22 MR. FITZSIMMONS: He's testified under oath.

23 THE COURT: I'm going to let him do it, Ms.
24 Mainigi. I think this is a Tempest in a Teapot and, until I
25 see the transcript, I'm not going to be able to tell whether

1 it's inconsistent or not, but so your objection will be
2 preserved for the record.

3 You go ahead, Mr. Fitzsimmons.

4 MR. FITZSIMMONS: Thank you, Judge.

5 Gina, would you put up starting with 129, 23, which is
6 the question?

7 BY MR. FITZSIMMONS:

8 Q. All right. Do you recall, Doctor, being asked the
9 question, as a West Virginia doctor, can you describe the
10 impact that the shipment of these -- this enormous amount of
11 pills has had on communities in West Virginia? And there
12 was an objection.

13 Your answer was, I have no clue. I mean, I know that
14 there was too many people on opioids because they're
15 prescribed too often by too many people. And there were
16 pill mills, as well, that were prescribed -- that were
17 selling opioids to people for cash with no medical records.

18 So, I know there was a lot of bad behavior by
19 prescribers and there was some good behavior by prescribers
20 who didn't know any better in retrospect.

21 MS. MAINIGI: Your Honor, I object on several
22 grounds. I object and ask this be stricken because it
23 clearly is not impeachment. This was just an avenue for Mr.
24 Simmons [sic] to read out loud a portion of a
25 mischaracterized answer of Dr. Deer's.

1 THE COURT: Well, it doesn't appear to me to be
2 inconsistent with what he testified to on the stand.

3 MS. MAINIGI: I ask that this prior back-and-forth
4 be stricken from the record, Your Honor.

5 MR. FITZSIMMONS: Judge, he said --

6 THE COURT: Well, I'm not going to strike it
7 because I can figure it out and I don't think it's
8 inconsistent. So, the weight I'm going to give it is pretty
9 minimal. Go ahead, Mr. -- if any. Go ahead, Mr.
10 Fitzsimmons.

11 BY MR. FITZSIMMONS:

12 Q. Doctor, as you sit here today, you have no information
13 or data as to how many pills were diverted into Cabell
14 County during the period of 2006 up to 2017; is that true?

15 A. No, sir, I do not.

16 Q. And you don't know how many pills were diverted into
17 Cabell County during that period of time that would be
18 considered -- that would be delivered by any of the
19 distributors that are defendants in this case; is that true?

20 A. No, sir, I do not.

21 Q. Are you aware of any document or seen anything from any
22 West Virginia state agency, board, board associations,
23 Medical Boards, or distributors, to stop monitoring for
24 orders of opioids that were suspicious for diversion?

25 MS. MAINIGI: Objection, Your Honor.

1 BY MR. FITZSIMMONS:

2 Q. Have you ever seen anything?

3 MS. MAINIGI: Excuse me. Objection. Outside the
4 scope. And I believe Mr. Fitzsimmons successfully objected
5 several times to me asking questions about distributors, so
6 I don't view this as any different.

7 THE COURT: I'll sustain the objection. I think
8 it's outside the scope.

9 BY MR. FITZSIMMONS:

10 Q. Doctor, you are not suggesting that because there was a
11 standard of care that doctors are immune from prescribing
12 opioids that are in excess or not medically warranted, are
13 you?

14 A. So, I'm trying to answer your question. So, if you
15 think about standard of care, if they're in excess for
16 non-medical reasons, it's definitely a breach. If they're
17 in excess because of poor education, they still may be
18 within the standard of care if they have done no harm.

19 So, could you re-word your question to me? I think
20 that's the best answer I can give you the way it's worded
21 currently.

22 Q. No. That's it. It's a sufficient answer.

23 You've actually -- you're in neuromodulation and that,
24 that's the type of treatment that you do; is that correct,
25 basically?

1 **A.** It's what we do most of our FDA studies on, yes, sir.

2 **Q.** And back in 2012, you do agree that there was an opioid
3 epidemic at that time here in West Virginia, in Cabell
4 County; is that right?

5 **A.** Yes, sir, I do.

6 **Q.** And you recall writing that guideline, one of the
7 authors, among others, called the Guidelines For a
8 Responsible Opioid Prescribing back in 2012; is that
9 correct?

10 **A.** Which one was that, sir? I'm sorry.

11 **Q.** It's the ASIPP. It's a two-part --

12 **A.** Oh, the ASIPP? Yes, sir. I believe I wrote the
13 neuromodulation section of that, along with Dr. Staats from
14 Hopkins.

15 **Q.** And in that --

16 MR. FITZSIMMONS: And it's Demo 275, counsel.

17 BY MR. FITZSIMMONS:

18 **Q.** In that, you were trying to reduce the incidence of
19 abuse and drug diversion at that time; is that correct? Is
20 that one of the purposes?

21 **A.** I think that was one of the goals. I think the other
22 goal was to give guidance to members of that society on how
23 to prescribe because they were mostly interventionalists and
24 it wasn't their primary area.

25 **Q.** All right. And the results of your study in putting

1 that guideline together, there was good evidence that
2 non-medical use of opioids is extensive and one-third of
3 chronic pain patients may not use prescribed opioids as
4 prescribed or may abuse them and illicit drug use is
5 significantly higher in these patients.

6 MS. MAINIGI: Objection, Your Honor.

7 BY MR. FITZSIMMONS:

8 **Q.** Is that correct?

9 MS. MAINIGI: Mr. Fitzsimmons is clearly reading
10 from a document. If the witness could be provided the
11 document, that would be helpful, because we cannot check to
12 see what's being read out loud.

13 MR. FITZSIMMONS: I thought I did. I said Demo
14 275.

15 MS. MAINIGI: Do you have an exhibit?

16 Your Honor, if Mr. Fitzsimmons could --

17 THE COURT: Show her the document.

18 MS. MAINIGI: -- pass along an exhibit, please.

19 MR. FITZSIMMONS: Your Honor, may I approach the
20 witness?

21 THE COURT: Yes.

22 BY MR. FITZSIMMONS:

23 **Q.** It's small print.

24 **A.** I'm okay with that. I have more trouble far away.
25 That is really small though.

1 All right. Which page, sir?

2 Q. Front page.

3 A. Front page? Okay.

4 Q. Yes, sir. I was reading results number one.

5 A. Okay. I'm with you, sir. Yes, I've read that section,
6 sir.

7 Q. Okay. So, did I read that correctly?

8 A. Yes, sir, I believe you did.

9 Q. And number 2 indicates, under results, there's good
10 evidence that opioid prescriptions are increasing rapidly,
11 as the majority of prescriptions are from non-pain
12 physicians. And then it goes on. Did I read that portion
13 correctly?

14 A. Yes, sir.

15 Q. Is there anything after that that changes the -- in
16 your opinion, the meaning of what I read?

17 A. No. I don't think so.

18 Q. All right. Number 3, there's good evidence that the
19 increased supply of opioids, use of high-dose opioids,
20 doctor shoppers, and patients with multiple co-morbid
21 factors contribute to the majority of the fatalities. Did I
22 read that correctly?

23 A. I think --

24 MS. MAINIGI: Objection, Your Honor. I don't
25 think that this document can serve as -- and objection that

1 the document is up. It's not been admitted into evidence.
2 And objection that Mr. Fitzsimmons is just reading out loud
3 from this document. He hasn't -- he's, himself, reading out
4 loud from the document. He's not asking Dr. Deer any
5 questions about the document.

6 THE COURT: Well, this is cross examination and
7 we've got to get through this and I can give it such weight
8 as it deserves, if any.

9 Go ahead, Mr. Fitzsimmons.

10 BY MR. FITZSIMMONS:

11 Q. Doctor, all right. You can put that document down for
12 now.

13 A. Okay.

14 Q. All right. So, you mentioned some characteristics of
15 West Virginians, medically importantly, I think, that you
16 believe were contributing factors to some increase of opioid
17 prescriptions in West Virginia; is that correct?

18 A. That's correct.

19 Q. Okay. And you can't quantify what increase there was
20 because you haven't done that tally or any research on how
21 much the increase was, whether it was a large amount or
22 small; is that correct?

23 A. That's correct.

24 Q. All right. So, the characteristics that you talk
25 about, and it's in your report, you mentioned and testified

1 here today to counsel for Cardinal that people in West
2 Virginia had hard labor, I guess -- I guess tougher type
3 jobs, physical, more physical jobs, and that that
4 contributed to an increase in the opioids; is that right?

5 **A.** I believe that's correct, yes, sir.

6 **Q.** And you saw that Pill Mountain with the date and it
7 shows the pills running from clear back in the 1990s, I
8 think up, and -- it peaks up around 2012, '14, area, takes a
9 dip and then starts down again after that. Do you remember
10 that?

11 **A.** Yes. Yes, sir.

12 MS. MAINIGI: Objection, Your Honor, to the
13 characterization of Pill Mountain.

14 BY MR. FITZSIMMONS:

15 **Q.** Did I fairly --

16 **A.** Yes, sir.

17 **Q.** -- characterize that?

18 THE COURT: Well, overruled. Go ahead.

19 BY MR. FITZSIMMONS:

20 **Q.** So, you talk about Cabell County. Do you know how many
21 coal -- and you mention in your report you cite a study from
22 the City of Huntington as your basis that City of Huntington
23 requested some grant, but they were talking about the entire
24 State of West Virginia, as opposed to Cabell County; do you
25 recall that?

1 **A.** I don't recall that but, certainly, I wouldn't dispute
2 it.

3 **Q.** All right. So, you were never provided with any
4 information about coal mining jobs in that county, were you?

5 **A.** In that county particularly, no.

6 **Q.** Okay. And that's one of the best known hard labor jobs
7 that we're all proud of, is our coal miners in this state,
8 right?

9 **A.** It used to be. We don't have as many jobs as we used
10 to, unfortunately.

11 **Q.** Well, I noticed that when you were asked by counsel the
12 question was stopped at 2008. It was 1998 to 2008. Do you
13 know how many -- how much coal was actually mined in Cabell
14 County during those years?

15 **A.** No, sir, I do not.

16 **Q.** Would it surprise you, and I have it here if anybody
17 wants to check, but there was zero coal mined not only from
18 that, but clear back from 1990 in Cabell County?

19 **A.** Yeah. Coal --

20 MS. MAINIGI: Objection.

21 THE COURT: He said he didn't know. I will
22 sustain the objection.

23 BY MR. FITZSIMMONS:

24 **Q.** So, you can't use that coal mining as a tough thing as
25 a reason for increase in pills in that county, can you?

1 MS. MAINIGI: Objection. Argumentative.

2 THE WITNESS: So, I wouldn't know the number of --
3 sorry, sir.

4 THE COURT: Overruled. You can answer that.

5 THE WITNESS: I wouldn't know the number of
6 chronic injuries from the past because a lot of these
7 chronic pain patients take around 30-40 years. There might
8 be some but, certainly, I can't quantify in any way. So, I
9 think you're right.

10 BY MR. FITZSIMMONS:

11 Q. And logging jobs, also, you mentioned. Do you know how
12 many logging jobs they have in Cabell County?

13 A. No. I don't know at all.

14 Q. Did the defense attorneys ever give you any information
15 on these jobs?

16 A. No, sir.

17 Q. Would you be surprised that there are none?

18 A. Logging would be more in like Ronceverte and Rainelle
19 and those areas, I would think.

20 Q. And you also mentioned construction jobs in Cabell
21 County. How many big buildings have you seen go up in
22 Cabell County that would have workers on it that were maybe
23 having harder labor that would, according to you, require
24 maybe a greater amount for treatment?

25 A. So, I have absolutely seen Marshall grow, as I've gone

1 through there. So, I think they do build some buildings
2 down there. St. Mary's has grown. Cabell has grown. So, I
3 think there are some construction jobs in Cabell County. I
4 don't -- I haven't quantified that in any way.

5 **Q.** And they -- they didn't provide you with any
6 information whatsoever as to the number of construction jobs
7 or any of the hard labor jobs; is that right?

8 **A.** That's correct.

9 **Q.** So, you also used age as a factor and West Virginia on
10 the average, we're all four years older than, I guess, the
11 average person in the United States or something like that.
12 So --

13 **A.** Our average age is four years older than the average
14 age of Americans.

15 **Q.** Did you know that as to the number of people over the
16 age of 65 that we're the fifteenth lowest in the entire
17 country? Did you know that?

18 **A.** I haven't seen those statistics. I would be happy to
19 look at them.

20 **Q.** Because they didn't provide you -- because nobody
21 provided you with those statistics, did they?

22 **A.** That's not what I'm familiar with from the report from
23 Bill Crouch's group, Health and Human Services, but it
24 certainly could be accurate.

25 **Q.** So, you talked a little bit about the opioid epidemic.

1 There are things being done to abate that epidemic that
2 you're actually participating in with the type of treatment
3 that you do?

4 **A.** Yes, sir.

5 **Q.** All right. All right. What's the name of your clinic,
6 Doctor?

7 **A.** Spine & Nerve Centers of the Virginias.

8 **Q.** And has it always been called that?

9 **A.** No. It was the Center for Pain Relief from '94 until,
10 I don't know, 2010 maybe. I don't remember when we changed
11 the name of that.

12 **Q.** And you changed the name? All right. So, you have
13 this 2006 paper also that you have authored. It's a
14 guideline, opioid guideline, and the management of chronic
15 non-cancer pain. Do you recall being one of the authors of
16 that article back in --

17 **A.** Which journal was that in, sir?

18 **Q.** That's in the Pain physician journal.

19 **A.** I don't recall that specifically, but I think it's Part
20 2 of the one you mentioned earlier maybe.

21 **Q.** Pardon me?

22 **A.** Is this the second version of the first one you
23 mentioned earlier?

24 **Q.** No. It's a separate guideline that you published.

25 **A.** Which one is --

1 MS. MAINIGI: Your Honor, objection. If I could
2 interject in here. If counsel could identify the exhibit
3 number and provide a copy, please.

4 MR. FITZSIMMONS: Yes. We intend to do that.
5 It's DEF-WV-02368.

6 Your Honor, may I approach the witness?

7 THE COURT: Yes.

8 THE WITNESS: Thank you, sir.

9 MR. FITZSIMMONS: Okay. That's small print, also.

10 THE WITNESS: Yes. This is an earlier guidance
11 than the previous, I believe. I think the previous was 12
12 this is 6.

13 BY MR. FITZSIMMONS:

14 Q. Right. Six years earlier?

15 A. Yes, sir.

16 Q. Looks like almost every five or six years you do a new
17 guideline.

18 A. I think that's pretty accurate because you have to see
19 what's happened in the research in that interim period of
20 time.

21 Q. I understand. And you probably haven't read this
22 recently, have you?

23 A. Probably not since 2006.

24 Q. Okay. All right. And on the first page, it says
25 background, opioid -- first of all, you're one of the

1 authors of this document, are you not?

2 **A.** It's a consensus document, so I would have written a
3 portion of it. And, usually, I would contribute to the
4 interventional parts of these things, not the whole
5 document.

6 **Q.** And it indicates in the first sentence, opioid abuse
7 has increased at an alarming rate. First sentence. Do you
8 see that?

9 **A.** Yes.

10 **Q.** Do you agree that back in 2006 it had been increasing
11 at an alarming rate?

12 **A.** Yes. We were seeing --

13 **Q.** Clear up -- I'm sorry.

14 **A.** We were starting to see issues with medications at that
15 point.

16 **Q.** It still had been increasing as late as 2012-2014, up
17 to that point; is that right?

18 **A.** I think that's accurate.

19 **Q.** Okay. And on Page 2, Doctor, the page in the upper
20 left-hand corner in the third full paragraph, it says,
21 however, documented abuse of opioids is increasing at an
22 alarming rate. Did I read that correctly?

23 **A.** I don't see where you are. I'm sorry.

24 **Q.** Oh, I'm sorry.

25 **A.** Page 2?

1 Q. It's on Page 2.

2 A. Can you highlight that for me? Okay. I see it now,
3 sir. Thank you.

4 Q. Okay. Did I read that correctly, Doctor?

5 A. Yes, sir, you sure did.

6 Q. In the United States with 4.6 percent of the world's
7 population, this is as of 2006, uses 80 percent of the
8 world's opioids. Did I read that correctly?

9 A. I believe that to be correct.

10 Q. Was that a true statement at that time?

11 A. I --

12 Q. 2006?

13 A. Yes, sir, it is. I would say that's most likely
14 accurate. That was from the DEA, Drug Diversion Control
15 Division, so they should know.

16 Q. And so, when we talk about the history of the standard
17 of care, you're in that middle category at that point, are
18 you not, 2006?

19 A. What do you mean by middle?

20 Q. I thought you broke it into three groups.

21 A. Oh, okay. You mean the phases? I wasn't sure where
22 you were going with that. So, the phase we discussed, that
23 would be in the middle phase at that point.

24 Q. We're in the 2006 time period when you write this,
25 right?

1 **A.** I think that was Phase 1 still, I believe. I would
2 have to see that. Will you show that? 2006, we were still
3 seeing it going up.

4 **Q.** Still going up, up until 2012-14, right in there?

5 **A.** '11 is when we started seeing some changes. So, up to
6 2010, it was still going up, but '11 to '15 was moderation.
7 And '15 until now --

8 **Q.** On Page -- Page 5, Doctor, it says on the left column,
9 second full paragraph down, as per the C-A-S-A, CASA. Do
10 you see that paragraph?

11 **A.** Yes, sir, I sure do.

12 **Q.** I'm going to read it. As per the CASA report, and CASA
13 stands for Center For Addiction and Substance Abuse, for the
14 bottom line is that the United States is in the throes, and
15 that's spelled t-h-r-o-e-s, of an epidemic of controlled
16 prescription drug abuse and addiction with 15.1 million
17 people admitting to abusing prescription drugs, dash, and
18 then it goes on. Did I read that correctly?

19 **A.** It appears that you did, yes, sir.

20 **Q.** Was that a true statement, 2006?

21 **A.** Again, this was most likely written by one of the
22 addiction people in this consensus. And so, I have no
23 reason to question if they would be accurate.

24 **Q.** Did you sign off on this document?

25 **A.** I would have been one of the authors, yes, sir. That

1 means 80 percent of the people would agree with every part
2 of it to be a consensus document.

3 **Q.** Is there anything that you have that you could show us
4 in the court today that you disagree with the paper that you
5 signed off as author or --

6 **A.** No, sir. No, sir. There is nothing I recall that I
7 would disagree with.

8 **Q.** All right. All right. Doctor, on -- on that same
9 page, far right column, about 13 lines up approximately, it
10 starts with the abuse of controlled prescription drugs.
11 Okay. So, let me just ask and -- excuse me. You guys write
12 a lot of medical articles. I think you said that you had
13 over 200 journal articles and things. That's part of your
14 research and stuff to help educate the -- usually other
15 medical personnel, but also the public?

16 **A.** That's correct.

17 **Q.** Okay. All right. And you've done a great deal of
18 authorship and trying to lead that charge and things that
19 are important to you or that you find that you think can be
20 helpful; is that right?

21 **A.** That's correct.

22 **Q.** All right. And so, it's important to make sure from a
23 science standpoint that people put these articles together
24 and write them accurately and truthfully; is that right?

25 **A.** I believe that's a true statement, yes, sir.

1 **Q.** That's why they have this process called peer review?

2 **A.** That's right.

3 **Q.** Now, is the pain management journal peer-reviewed?

4 **A.** Yes, sir.

5 **Q.** This one is peer-reviewed? So, the article we're
6 talking about right now was peer-reviewed?

7 **A.** We would have had usually three people review the
8 article that were objective and make edit recommendations.
9 And then, in order for it to be accepted for publication,
10 you have to make a response to those edits. So, this would
11 have gone through a peer review with at least three people.
12 That's the standard for most journals. Some use four or
13 five reviewers. So, that's what you would do.

14 **Q.** All right. So, is there a process that if you don't
15 agree with the article, that you file some note or something
16 or objection?

17 **A.** Well, I think if you didn't agree with the article as a
18 whole, you would take your name off the article, I would
19 think.

20 **Q.** Take it off?

21 **A.** If you don't agree with portions of it, you can either
22 find a middle ground, which often happens, or there's
23 certain areas where you have no expertise at all and you
24 have to defer that to your colleagues who are the experts in
25 that area and you trust them to write that section.

1 So, not to be long-winded. For example, when we're
2 writing about neuro submission guidelines, which I have four
3 coming out the next few months, the part on brain
4 stimulation for Parkinson's tremor, I didn't write that
5 part. I have really no knowledge of that part. My
6 colleague, Jeff Arle, at Harvard wrote that part so far and
7 some other folks. And so, I trust his expertise.

8 So, I would -- I would sign on as an agreeing author,
9 but I wouldn't have any expertise in the area of brain
10 stimulation for Parkinson's, just to give an example of
11 that.

12 **Q.** So, in other ways, you could file a comment and say I
13 don't agree with this one line?

14 **A.** If you didn't agree, you could file a comment, if you
15 chose to, or if you trust the person with expertise, you
16 would just sign off on it because you trust what they say.

17 **Q.** Trustworthy even though you aren't the specialist,
18 right?

19 **A.** Well, you often have one of the experts in the world
20 writing that part. So, you assume they're chosen because
21 they are the expert on that part.

22 **Q.** Can we agree, Doctor, you didn't write anything about
23 this article whatsoever to disavow, disagree, or say I've
24 got a hunch it might not be right or even close?

25 **A.** I'm not saying today I disagree either. I'm just

1 saying I wouldn't have written parts that aren't to do with
2 procedures usually, but I would have, you know, read those
3 parts and, certainly, I don't recall disagreeing with them.

4 **Q.** All right. Let me read then the thirteenth line up.
5 It says the abuse of controlled prescription drugs was
6 foreshadowed by dramatic increases in their manufacture and
7 distribution and the number of prescriptions written and
8 filled. And then it has a cite. Did I read that correctly?

9 **A.** It appears that you have.

10 **Q.** Was that a true statement when you made it as a part of
11 an author of this paper?

12 MS. MAINIGI: Objection, Your Honor. This is well
13 outside the scope, the distribution and manufacture, as Mr.
14 Fitzsimmons already established several times during the
15 direct exam. It is outside the scope of this witness's
16 expertise.

17 THE COURT: Well, overruled. You can answer the
18 question. Go ahead.

19 THE WITNESS: I would assume if you write a
20 prescription, someone has to distribute that prescription.
21 That's about the length of my knowledge of distribution.

22 BY MR. FITZSIMMONS:

23 **Q.** Because you had some some of the most intelligent
24 researchers in this area that were making that statement in
25 2006, right?

1 **A.** Well, I think there's some smart people on that paper,
2 yeah.

3 **Q.** And then, on Page 8, Doctor, and I just have a few
4 more questions, I think, and we'll be done, but Page 8 under
5 the title drug diversion for your paper?

6 **A.** Yes, sir.

7 **Q.** Do you see that?

8 **A.** Yes, sir, I do.

9 **Q.** All right. I'm going to read it to you.

10 MR. FITZSIMMONS: Can you highlight that, Gina,
11 for the doctor and for the judge? Just go down, the first
12 sentence, I think. Got it? Okay. So, just the first
13 sentence, can you highlight that, down to distribution
14 process?

15 BY MR. FITZSIMMONS:

16 **Q.** All right. Dr. Deer, I think you said it's been a long
17 time. You have not seen this article or that provision or
18 anything like that for probably your guess is back to 2006;
19 is that right?

20 **A.** No. I mean, you asked me if I had read it. I haven't
21 read the full article. I may have looked at the article at
22 some point, but I don't --

23 **Q.** You may have seen --

24 **A.** I don't recall reading the whole article, no.

25 **Q.** You haven't studied it; is that fair to say?

1 **A.** That's fair to say.

2 **Q.** Or even in preparation for this trial, you haven't been
3 through it?

4 **A.** Well, I've looked at the overall beginning of these
5 articles, but I didn't read the whole article, I don't
6 believe.

7 **Q.** All right.

8 **A.** But we're looking at it now.

9 **Q.** Okay. Let me read it to you. This is a statement made
10 by your paper in 2006, when we had an alarming rate of
11 increase of opioid at that time being prescribed, right, a
12 crisis, epidemic in this country. And your paper says drug
13 diversion in boldface print, Section 3.7. Did I read that
14 correctly?

15 **A.** Yes, sir, you did.

16 **Q.** And then it says drugs can be diverted from their
17 lawful purpose to illicit use at any point in the
18 pharmaceutical manufacturing and distribution process.

19 Doctor, you would not have written that statement
20 unless it was true at that time or authored it; is that
21 true?

22 MS. MAINIGI: Objection. Foundation. I don't
23 think it's been established that he wrote that statement,
24 Your Honor.

25 THE COURT: Well, can you clear that up, Mr.

1 Fitzsimmons?

2 BY MR. FITZSIMMONS:

3 Q. You're the author of this paper. You review it, right?

4 A. So, let me make sure we're on the same page.

5 Q. Sure.

6 A. I was an author of this paper.

7 Q. You are an author?

8 A. I wouldn't have written this section, but I don't have
9 any reason to think it was incorrect. The person who would
10 have written this section would have been someone with
11 expertise in diversion and addiction, not me, but I would
12 have signed off on the paper at the time because I would
13 trust their judgment.

14 And, usually, you have to cite what you say. There
15 should be a citation somewhere in that section of what
16 they're talking about. I assume there is a citation, but
17 that -- that's how it usually works. They cite something
18 and they write it and, again, this is way outside of my area
19 of expertise. I'm not an expert in that area, but whoever
20 wrote that portion would have been someone who the society
21 felt was an expert in addiction and diversion.

22 THE COURT: So, if I heard him correctly, he
23 didn't write it, but he doesn't disagree with it.

24 BY MR. FITZSIMMONS:

25 Q. You don't disagree with it as an author and you have a

1 duty to actually step up and disagree if you do disagree and
2 you didn't do that?

3 **A.** I think if I had a major disagreement with anything in
4 any paper, you and I are just meeting, but I'm not quiet. I
5 would have spoken out with a major disagreement. And this
6 section is more that I would defer to the expertise of
7 someone else because I have no expertise in diversion.

8 **Q.** All right. So, Doctor, from 2006 then to 2012, if you
9 pull that thing called IQVIA, have you ever heard of that?

10 **A.** Yes, sir.

11 **Q.** You're familiar with that? You've seen their stats?

12 **A.** Yes, sir, I have.

13 **Q.** Okay, sure.

14 MR. FITZSIMMONS: So, Gina, could you get P-41960?
15 Is that right, Mr. Farrell, 41960? That's it.

16 MS. MAINIGI: Your Honor, I have an objection.

17 THE COURT: Okay.

18 MS. MAINIGI: There's been no foundation laid for
19 this document. It's not in evidence. We have no
20 authentication of this document that has occurred by any
21 prior witness or fact witness. The witness has not seen
22 this document before. I don't think there's a basis to be
23 putting it on the screen.

24 I don't think --

25 THE COURT: Well, he said he -- he was asked if he

1 heard of IQVIA and he said yes. And he said you're familiar
2 with that and seeing their stats? And he said, yes, sir, I
3 have.

4 Go ahead, Mr. Fitzsimmons.

5 MR. FITZSIMMONS: Thank you.

6 Judge, may I approach the witness?

7 THE COURT: Yes.

8 MR. FITZSIMMONS: Thank you.

9 MS. MAINIGI: Your Honor, my objection, if I may,
10 is -- continues to the specific stats that are described
11 here, which are not statistics. I think a foundation needs
12 to be laid and Gryphon, as I understand it, is simply the
13 plaintiffs' consultants. No one from Gryphon has come to
14 testify about these numbers.

15 THE COURT: Well, I'll overrule the objection.
16 This is cross examination and wide latitude is to be allowed
17 and I think this provides a good faith basis for the
18 questions to be asked.

19 So, you go ahead, Mr. Fitzsimmons.

20 BY MR. FITZSIMMONS:

21 **Q.** So, Dr. Deer, you've actually seen these types of
22 statistics, I think you said?

23 **A.** Not -- not this particular thing --

24 **Q.** Not that format?

25 **A.** Not this particular company.

1 Q. You've been told about your rankings though, that --

2 A. Well, I know we are the largest practice in the State
3 of West Virginia, referral only. So, obviously, I know the
4 trends of our practice mirrors the State of West Virginia.

5 Q. Okay. All right. So, this is -- tracks a period of
6 20 years, okay? And does that appear correct to you?

7 A. Yes.

8 Q. And this is tracking the prescribing rate for you as a
9 doctor, Timothy Deer?

10 A. Myself and my nurse practitioners, who also write.

11 MS. MAINIGI: Objection again, Your Honor.

12 Foundation. I don't think he can lay a foundation with this
13 particular witness with the questions.

14 THE COURT: Overruled. Let's get through this.
15 Go ahead, please.

16 THE WITNESS: Myself and my nurse practitioners,
17 who I also write the prescriptions for --

18 BY MR. FITZSIMMONS:

19 Q. And during -- during --

20 COURT REPORTER: I'm sorry. Myself and --

21 THE WITNESS: Myself and my nurse practitioners,
22 who I also write the practitioners for the nurse
23 practitioners.

24 BY MR. FITZSIMMONS:

25 Q. You write prescriptions for other doctors?

1 **A.** I think you're misquoting what I just said, sir.

2 **Q.** I didn't hear.

3 **A.** I said our nurse practitioners do not write Schedule
4 IIs. I will write that prescription if it's received
5 together.

6 **Q.** So, you write them for the nurse practitioners that are
7 prescribing?

8 **A.** No, that's not true. That's not what I said. You
9 continue to take me out of context. I said when a nurse
10 practitioner sees a patient with me, we would actually write
11 that prescription.

12 **Q.** So, Doctor, looking at the chart from 1997 to 2017, you
13 were in the top five ranked in the county in prescribing
14 opioids; is that correct?

15 **A.** In Kanawha County?

16 **Q.** Yeah, up until 2017. In Kanawha County, yes.

17 **A.** I would think that would be correct because of our
18 population we see, yes.

19 **Q.** Right. And if you go all the way over to the MMEs,
20 you're in the top two or three for about 12 years and then
21 you drop down to number five up until 2017. And then
22 there's a drastic change in 2017; is that right?

23 **A.** I'm 116th in the state in '17. That tells me what a
24 good job we were doing. Yes, we were --

25 **Q.** Could you answer the question?

1 **A.** I'm answering that. So, yeah, I do see that increase
2 and I see we're down to 116th in the state by '17.

3 **Q.** And let's talk on Page 3 of that exhibit, bottom table,
4 Table 5. Do you see that? It's a -- 20-year history?

5 **A.** Yes, sir, I do.

6 **Q.** Now, this is during the same time period we talked
7 about opioids rising at an alarming rate, crisis, epidemic
8 in your papers from 2012 to 2006. That this was an alarming
9 rate and problems at that time. Generally, that's the time
10 period we're talking here; is that right?

11 **A.** I think this is from '97 to '17. So, this is a longer
12 time period.

13 **Q.** All right. And during that period of time for
14 prescribing hydrocodone in your county, which is Kanawha
15 County, you were the second highest prescriber of
16 hydrocodone, which is an opioid; is that correct?

17 **A.** That's correct.

18 **Q.** And you were the first number one for oxycodone, which
19 is another opioid in Kanawha County during that same period
20 of time; is that right?

21 **A.** For the ten-milligram strength, not for the five.

22 **Q.** And there's three types of fentanyl, different --
23 different quantities to the fentanyl? There's a .1, .075
24 and a .05; is that right?

25 **A.** That's correct.

1 Q. And for fentanyl, which is a -- it can be a lethal drug
2 and it is one in the overdoses; is that right?

3 A. So, not in this form, no, that's not correct, sir.

4 Q. Is fentanyl a -- can be a lethal drug?

5 A. You asked me about this particular graph. These are
6 fentanyl patches for cancer patients and I don't know of any
7 fatality at all in our practice from that because I would
8 have known from the committee we talked about. So, the
9 answer would be, in this group of people, which is about
10 98 percent cancer patients, I don't know of any fatalities
11 from fentanyl patches. You're talking about injected
12 fentanyl by people out by the bus station. That's a
13 different group of people.

14 Q. So, were you ranked as number one fentanyl prescriber
15 for all three versions of the fentanyl under that table?

16 A. Kanawha County, I would have been probably the only
17 person prescribing that drug for the cancer population.

18 Q. And so, fortunately, somebody did a graph of your
19 prescriptions of opioids so we could kind of look at the
20 Pill Mountain and your prescription habits from clear back
21 in 2000.

22 MR. FITZSIMMONS: Gina, could you put the last
23 page on there, Page 4, please? Oh, it's on there? All
24 right.

25 BY MR. FITZSIMMONS:

1 Q. So, the blue -- reading this is pain medicine. These
2 are all the specialists in pain medicine. You're a
3 specialist. And this goes from 20 -- or it goes from even
4 before 2000 all the way through 2017, this chart. This is a
5 20-year period --

6 A. Correct.

7 Q. -- being graphed out. The bottom blue is for all pain
8 specialists, people exactly in your specialty, as to what
9 they were prescribing in opioids. Is that what that shows?

10 A. That's incorrect.

11 Q. Is that what the graph says?

12 MS. MAINIGI: Objection. Foundation. Your Honor,
13 there's -- this witness has not seen the graph. He doesn't
14 know whose data is contained within this graph.

15 THE WITNESS: So, I would say -- oh, sorry.

16 THE COURT: Overruled. Answer the question.

17 THE WITNESS: No. That's incorrect because
18 anybody that does pain medicine at all, you could do
19 anesthesia four days a week and you can do pain one, which
20 is very common around the country. Then you would be
21 considered pain medicine, but you may do maybe four days of
22 pain medicine. If you're an academic center like Dr.
23 Gilligan, you don't write prescriptions at all. Your
24 residents and fellows write for you. So, this graph is
25 totally incorrect and misleading. I don't know who

1 developed it, but it's totally wrong.

2 **Q.** Doctor, okay. As to the graph at the upper left-hand
3 corner right after the title, which the title says physician
4 dosage units compared to specialty averages, hyphen, Timothy
5 Deer. IQVIA, West Virginia, 1997 to 2017. Right underneath
6 that is a little descriptor of what the colors blue, red and
7 green for the three graphs that are drawn on that chart; do
8 you see that?

9 **A.** I do.

10 **Q.** And under the blue one, the first one, does it say pain
11 medicine?

12 **A.** It says that.

13 **Q.** All right. And blue would be on the graph, the bottom
14 one; is that correct?

15 **A.** Correct.

16 **Q.** And then it has red, which is pain -- says pain
17 medicine. Did I read that correctly?

18 **A.** You did.

19 **Q.** And that's the one, the lower one there; is that
20 correct?

21 **A.** Correct.

22 **Q.** And then, the green is what they have for you; is that
23 right?

24 **A.** Correct.

25 **Q.** All right. Do you -- do you notice any resemblance

1 with that in the pill mountain, Doctor, as to the
2 prescribing?

3 **A.** I do think that our practice mirrors what happened in
4 West Virginia since we are referral-only. So, I think that
5 is what I -- that really reestablishes what I said earlier
6 on multiple occasions. We do follow our referral base.

7 You see now in '17 we're way below anyone on that
8 graph. But I also will tell you that the other two lines
9 without full-time pain practices are large groups. So, I
10 think this is a misrepresentation of data, which is really,
11 I think, unfortunate.

12 But having said that, I'm really happy that, by '17,
13 we're well below anyone and I think that goes back to the
14 work we've done to eliminate opioids now that we've taken
15 more people off opioids than anyone in the State of West
16 Virginia, maybe the whole country.

17 **Q.** And when did you start -- or did the practice pick up
18 on the neuromodulation that you were actually selling
19 devices and you do -- and it's kind of like a TENS unit, the
20 electrical stimulators and things like that. I know that
21 was one of the early versions, but do you do that type of
22 treatment where somebody gets electrical shock and it kind
23 of stops the nerve from transmitting the signal? That's
24 kind of an example, but that's my understanding.

25 **A.** So, I think that the way you explained that is really

1 hard for me to answer. So, if you're okay with it, I'll
2 clarify the question.

3 **Q.** Would you, please? Thank you.

4 **A.** So, we have been doing neuromodulation since 1993, but
5 really in the last ten years, our work with the FDA devices
6 and really establishing new software and artificial
7 intelligence, actually, for the spine has really been
8 evolving greatly. So, that's in the last five years. Our
9 success of FDA approval of new devices and utilization has
10 really grown tremendously.

11 So, from '15 on, we've seen devices much more
12 effectively. We've also developed peripheral nerve devices
13 for nerves and extremities. So, again, most of those people
14 come in and come out of our practice off opioids. That's a
15 major tool we've used to reduce that and we have the data
16 from our medical students that show that very clearly.

17 COURT REPORTER: Can you please slow down for me?
18 I'm really sorry.

19 THE WITNESS: I'm sorry. We do -- I'll do better.
20 We have the data from our research that shows that very
21 clearly, that if you come to our practice on a high risk
22 opioid, which this doesn't reflect this. This is a horrible
23 graph, but in the data, you have about an 80 percent chance
24 of getting off your opioid or being reduced by half.

25 The problem we had back in 1997 to 2015, they kept

1 coming in high volumes to our practice because we are the
2 only center for Southern West Virginia. So, I think that's
3 really representative of that and it does mirror the
4 practice in West Virginia quite well.

5 So, the answer would be, we've been doing those
6 therapies for a long time. For the last five years or so,
7 our success rates have climbed down to about 80 percent. We
8 were about 50 percent before based on just technology
9 improvements.

10 **Q.** Are you done with your answer?

11 **A.** Yes, sir, I am.

12 **Q.** All right. So, in 2017, is that around when you
13 changed the name and got rid of the other name?

14 **A.** No, that's not true. I think it was earlier than that.
15 I think. I don't think it was '17. Could be, but I don't
16 think so.

17 **Q.** Around that time?

18 **A.** I think about '15 or so.

19 **Q.** People were criticizing pain clinics and things like
20 that?

21 **A.** I didn't like the name because I think it didn't
22 represent what we do, as well, because most of our studies
23 are on the spine and nerves.

24 **Q.** And can you explain this chart? I mean, its highest
25 level also now just falls off the chart almost here in the

1 last couple of years. You don't prescribe any opioids now?

2 MS. MAINIGI: Objection, Your Honor. Once again,
3 Mr. Deer -- Dr. Deer did not put this chart together. He
4 has no idea where the data came from. So, he can't explain
5 it. There's no foundation laid for this data.

6 THE COURT: Well, I think it provides a good faith
7 basis for the questions and I think he's explaining his
8 answers very effectively. So, I'm going to allow it.
9 Overruled.

10 THE WITNESS: So, I don't -- I don't start new
11 patients on opioids ever. That's not something I do. We
12 actually take over opioids from referring sources from all
13 over the place and then we try to bring them off. So, what
14 you're seeing there is, I think from that data that I --
15 again, it's incorrect.

16 What you're seeing, though, overall is that as we are
17 more successful, as we have been in people getting off
18 opioids, our referral base has, because of the things we
19 talked about, CDC, SEMP guidelines, and the 2018 law, they
20 are sending us people now who they haven't started yet.

21 If you're not on opioids when you come to see us, your
22 odds are you'll never be on opioid. So, I think you're
23 seeing now our referral base changing because we're a
24 reflection of the referral base in Southern West Virginia.
25 And then, you're seeing our success we've had for sometime

1 now, getting about 80 percent of the people off opioids, and
2 sometimes more than that.

3 And sometimes, totally eliminating an opioid, but when
4 we don't eliminate it, we may reduce it by at least half.
5 So, I think we've had great success. But the funnel of new
6 people coming in has improved dramatically, is what we're
7 seeing.

8 MR. FITZSIMMONS: Judge, I think I probably --
9 could we take break ten minutes early? I think --

10 THE COURT: Yeah. It's time for a break anyway.
11 Let's come back at 3:30.

12 You can step down, Doctor, during the break.

13 THE WITNESS: Thank you.

14 THE COURT: We'll be in recess until 3:30.

15 (Recess taken)

16 (Proceedings resumed at 3:29 p.m. as follows:)

17 THE COURT: You can resume the stand, Dr.
18 Deer.

19 All right, Mr. Fitzsimmons, go ahead.

20 MR. FITZSIMMONS: No further questions, Judge.

21 MS. MAINIGI: Your Honor, just a few.

22 REDIRECT EXAMINATION

23 BY MS. MAINIGI:

24 Q. Dr. Deer, I don't know --

25 MS. MAINIGI: Gina, can you put up that chart that

1 you had up before, the one that we had up?

2 BY MS. MAINIGI:

3 **Q.** Okay. Dr. Deer, we were looking at this chart with
4 Mr. Fitzsimmons right before we broke. Do you have any
5 idea how the data was collected for this chart?

6 **A.** I do not.

7 **Q.** And you don't know who Gryphon is, do you?

8 **A.** I do not.

9 **Q.** You don't know who Ann Ritter at Motley Rice is, do
10 you?

11 **A.** I do not.

12 **Q.** And it seems like those are the people involved in
13 gathering this information; is that correct?

14 **A.** Yes, ma'am.

15 **Q.** So let's look at this chart, though, and in particular
16 the components of it. So where it says "pain medicine," do
17 you have any idea who the doctors are that went into that
18 sample?

19 **A.** No, I don't actually.

20 **Q.** And you have a couple of specialties. You're an
21 anesthesiologist. You also specialize in pain medicine. Is
22 that correct?

23 **A.** That's correct.

24 **Q.** And I take it there aren't very many people like you in
25 West Virginia. Is that fair?

1 **A.** I think we have about six people who do full-time pain.

2 **Q.** And you don't know if the folks in pain medicine as
3 defined by the Gryphon in this chart included those six
4 people or included a broader range of anesthesiologists;
5 right?

6 **A.** We have probably 200 that do anesthesia with a little
7 bit of pain. And they're considered pain medicine too by
8 many because they do one day a month or one day a week.

9 **Q.** So if you were compared to six other people versus 200
10 people, that would really affect the numbers; correct?

11 **A.** Well, anesthesiologists generally do part-time pain,
12 treat more -- do more injections because they don't follow
13 patients chronically.

14 **Q.** And, so, they may not be prescribing opioids very
15 often?

16 **A.** That's correct. That's true nationwide, not just in
17 West Virginia.

18 **Q.** Now, I think you were asked a question about -- a few
19 questions about coal mining.

20 We can take that down.

21 Are you familiar with Mayor Steve Williams of
22 Huntington?

23 **A.** I know the name.

24 **Q.** Okay. And are you aware that the City of Huntington,
25 as led by Mayor Williams, has actually said the following;

1 that the continuing economic distress --

2 MR. FITZSIMMONS: Judge, --

3 BY MS. MAINIGI:

4 Q. -- due to coal --

5 THE COURT: Just a minute.

6 MR. FITZSIMMONS: Could I have a citation for what
7 she's referencing?

8 MS. MAINIGI: Yes. I am citing the Mayor's
9 Institute Case Statement, Defendants' West Virginia 902.
10 It's a document. This is redirect, so I wasn't aware of
11 what you were going to ask on cross so I don't have a copy.

12 MS. KEARSE: I think we have a copy.

13 MS. MAINIGI: Okay. If you want to pull it up,
14 that's fine. I just have one question about it.

15 MR. FITZSIMMONS: I'd like to look at the
16 document, please.

17 THE COURT: You may.

18 BY MS. MAINIGI:

19 Q. Okay. So, Dr. Deer, are you aware that the City of
20 Huntington --

21 MR. FITZSIMMONS: Judge, I'm still reading the
22 document.

23 MS. MAINIGI: Your Honor, I don't know why that
24 would prevent me from asking a question.

25 THE COURT: Go ahead, please.

1 BY MS. MAINIGI:

2 **Q.** Are you aware that the City of Huntington has said
3 that, quote, continuing economic distress due to coal
4 and manufacturing decline has intensified the spread of
5 opioid use in Huntington to unthinkable proportions, end
6 quote?

7 Were you aware of that?

8 **A.** I was not aware of that.

9 **Q.** Does it make sense to you what the Mayor said?

10 **A.** It does because if you have an economy or city that's
11 bigger than smaller cities around it, you're impacted by the
12 decline of employers in your region.

13 **Q.** And did you tell us that you come from a family of coal
14 miners?

15 **A.** Yes. My dad worked at Island Creek Coal in Kelly, West
16 Virginia, and my grandpa in the same mines, and my other
17 grandpa at Slider's Creek as a strip-miner.

18 **Q.** Thank you, Dr. Deer.

19 THE COURT: Do you have anything further of this
20 witness?

21 MR. FITZSIMMONS: Nothing further.

22 THE COURT: May --

23 Mr. Hester.

24 MR. HESTER: Yes, Your Honor. I was just ready to
25 call my next witness.

1 THE COURT: Oh, okay.

2 Dr. Deer, thank you, sir, very much.

3 THE WITNESS: It's been a real honor to be here.
4 Thank you so much.

5 THE COURT: Glad to have you. Good luck to you.

6 MR. HESTER: Your Honor, the defendants call
7 Dr. James Hughes to the stand.

8 THE COURT: Okay.

9 THE CLERK: Sir, please state your name.

10 THE WITNESS: James Hughes.

11 THE CLERK: Thank you. Please raise your right
12 hand.

13 **JAMES HUGHES, DEFENDANTS' WITNESS, SWORN**

14 THE CLERK: Thank you. Please take a seat.

15 THE COURT: Good afternoon, Dr. Hughes.

16 THE WITNESS: Good afternoon, Your Honor.

17 DIRECT EXAMINATION

18 BY MR. HESTER:

19 **Q.** Good afternoon, Dr. Hughes.

20 **A.** Good afternoon.

21 **Q.** Could you please introduce yourself to the Court?

22 **A.** My name is James Hughes of Belgrade, Maine.

23 **Q.** And what is your field of specialty, Dr. Hughes?

24 **A.** I am an economist who specializes in applied
25 microeconomics, mainly labor economics and health economics.

1 **Q.** And could you describe what health economics is?

2 **A.** Sure. Health economics is the study of the markets
3 that get health services distributed. And it merits a
4 special field because the markets in health economics are
5 very different from the markets, say, for appliances or
6 automobiles or other articles.

7 For example, in pharmaceuticals the, the person who
8 decides what product is going to be purchased is not someone
9 who actually is paying for it or is consuming it. And
10 that's very different from markets in other areas of
11 economy.

12 **Q.** And does health economics include the study of public
13 and private insurance companies and other entities that pay
14 for healthcare services in the United States?

15 **A.** Yes, it does.

16 **Q.** And are those entities sometimes referred to as payers?

17 **A.** They are.

18 **Q.** Could you give me some examples of payers?

19 **A.** Sure. So payers are among the ones that you might
20 think of, CIGNA, United Healthcare. But it also includes
21 government agencies like Medicare, Medicaid, and in the
22 State of West Virginia the Public Employees Health -- excuse
23 me -- Public Employees Insurance Association.

24 **Q.** So, Dr. Hughes, we're going to get into your opinions
25 in more detail. But at the very highest level of

1 generality, what were you asked to do in this case?

2 **A.** I was asked to examine the role of these payers in the
3 prescribing of opioids in West Virginia.

4 **Q.** So before we delve into your opinions, I'd like to give
5 the Court a sense of your background. What's your
6 educational background?

7 **A.** I have a BA in International and Comparative Studies
8 from Boston University; a Master's Degree in Economics from
9 Boston University; and a Ph.D. in Economics from the
10 University of Michigan.

11 **Q.** And between the time that you got your Master's Degree
12 in Economics and your Ph.D., did you, did you work in
13 various pursuits?

14 **A.** I did. I worked at the United States Environmental
15 Protection Agency. I worked at the OECD in Paris. I worked
16 at SRI International in Palo Alto, and also for the Rand
17 Corporation briefly.

18 **Q.** And at a high level, what did your work as an economist
19 detail during those years?

20 **A.** I was either the author or supervisor of reports that
21 examined how economic incentives could make the regulatory
22 system more efficient and improve compliance with
23 regulations.

24 **Q.** So after you earned your Ph.D., Dr. Hughes, what did
25 you do then?

1 **A.** After I earned my Ph.D., I started as an Assistant
2 Professor at the State University of New York at Albany.

3 From there, I moved as an Assistant Professor to
4 Amherst College in Massachusetts, and then to Bates College
5 in Lewiston, Maine, as an Assistant Professor. Over time, I
6 became an Associate Professor and then a Full Professor.

7 **Q.** And you mentioned these years as a Professor at
8 different colleges and universities. A Professor in what,
9 Dr. Hughes?

10 **A.** I'm sorry. Professor of Economics.

11 **Q.** And what is your current position?

12 **A.** I am a -- at Bates College I am Professor of Economics
13 Emeritus.

14 **Q.** And what is Bates College?

15 **A.** It's a small liberal arts college in Maine.

16 **Q.** And how would you describe the reputation of the
17 economics department at Bates College?

18 **A.** I think the college was quite proud of its economics
19 department. There was a study that ranked the Bates
20 economics department as second in the country in the number
21 of times that our colleagues' research was cited by other
22 researchers.

23 **Q.** And do you hold a current title at Bates College?

24 **A.** Yes. I am the Thomas Sowell Professor of Economics
25 Emeritus.

1 Q. And, so, you refer to an Emeritus position. Does that
2 mean you're retired?

3 A. I am indeed.

4 Q. And when did you retire?

5 A. July 30th, 2020.

6 Q. And before you retired, were you a tenured member of
7 the faculty?

8 A. I was.

9 Q. And what does it mean that you're the Thomas Sowell
10 Professor?

11 A. The Thomas Sowell Professorship is what's called an
12 Endowed Chair. It's a title that is funded by a donation
13 from a benefactor and it's awarded -- it's a higher honor
14 than simply being a Full Professor.

15 Q. And before you retired from, from your teaching role,
16 what kind of classes did you teach at Bates College?

17 A. I taught most everything in applied microeconomics. I
18 taught health economics, labor economics, environmental
19 economics, economics of intellectual property, introductory
20 and intermediate microeconomic theory, introductory
21 macroeconomic theory. And there's probably some others I'm
22 not remembering.

23 Q. Let me ask you about your teaching in health economics
24 specifically. Did that include a focus on health insurance
25 as part of a course on health economics?

1 **A.** Yes, it did. In fact, the first time I taught health
2 economics in the '90s, we structured the entire course
3 around what was at the time called Hillary Care, President
4 Clinton's failed but proposed health insurance scheme.

5 **Q.** And, so, did that involve looking at the interactions
6 between insurers and payers, patient prescribers and the way
7 that medicine gets dispensed in the United States vis-à-vis
8 insurance? Was that a core part of what you were doing?

9 **A.** Yes, I mean exactly. That proposal would have affected
10 pretty much every aspect of the health delivery system,
11 including insurance, payers, pharmaceuticals, hospital
12 services and the like.

13 **Q.** And did you teach on the subject of health insurance
14 over a number of years while you were at Bates?

15 **A.** Yes, I've taught health insurance on a number of
16 occasions.

17 **Q.** And --

18 **A.** I'm sorry, health economics on a number of occasions.

19 **Q.** And that included health insurance?

20 **A.** Yes, it did.

21 **Q.** Have you received any awards or honors for your
22 teaching?

23 **A.** Yes. I am happy to say I've been the only person to
24 win the Kroepsch Teaching Award at Bates twice.

25 **Q.** And what is the Kroepsch Teaching Award?

1 **A.** It's a teaching award that is awarded based on student
2 input.

3 **Q.** And aside from your teaching role, did you hold any
4 leadership positions in the economics department at Bates?

5 **A.** In the economics department I served as Department
6 Chair for about six years.

7 **Q.** And what did that role entail?

8 **A.** That was basically organizing the teaching and advising
9 duties of the economics faculty, but also responsibility for
10 promoting the interests of the department both within the
11 college and outside the college.

12 **Q.** Did you serve on any college committees that had
13 interactions with insurers?

14 **A.** Yes. I was a member and sometimes chaired what was
15 called the Ad Hoc Benefits Committee. And that was a
16 committee that reviewed insurance proposals, health
17 insurance proposals, and chose the insurance program that
18 the college would offer to its faculty and staff.

19 **Q.** In addition to your teaching role, Dr. Hughes, is
20 research another major component of your professional work?

21 **A.** It is.

22 **Q.** And on what topics have you engaged in that kind of
23 research?

24 **A.** I have engaged in research in labor economics and
25 health economics, and also on the prescription drug

1 industry.

2 **Q.** And have you received grant funding for your research?

3 **A.** Yes. I received several minor and one major grant for
4 my research from Bates College. And then after my
5 dissertation, I received a major grant from the Robert Wood
6 Johnson Foundation, which is a renown funding agency in the
7 area of healthcare.

8 **Q.** And have you published academically?

9 **A.** I have.

10 **Q.** And about how many peer-reviewed papers have you
11 published?

12 **A.** Approximately two dozen.

13 **Q.** And have you given lectures nationally and
14 internationally related to your research?

15 **A.** Yes. I've given several lectures both around Maine,
16 around the country, as well as places like Berlin,
17 Amsterdam, Hong Kong, or Beijing.

18 **Q.** And we're talking about your research work. Has some
19 of that research involved health insurance in the
20 pharmaceutical industry?

21 **A.** Yes.

22 **Q.** And have you done any research into the economics of
23 substance abuse?

24 **A.** Yes, I have. I had a post-doctoral fellowship at the
25 Brandeis University Heller School. I believe it's the

1 Heller School for Public Health. And that was -- I was the
2 co-author of studies on substance abuse and substance abuse
3 treatment.

4 **Q.** Have you done other research on the pharmaceutical
5 industry?

6 **A.** Yes. In the course of my consulting work, I have done
7 extensive research on the pharmaceutical industry.

8 **Q.** And about how many years does that span?

9 **A.** About 25 years.

10 **Q.** And is much of that work published?

11 **A.** No. Unfortunately, I believe that much of this work
12 would be publishable but, unfortunately, the data that I was
13 using in my consulting work was all confidential. So I was
14 not able to publish it.

15 **Q.** Now, you mentioned 25 years of research work related to
16 the pharmaceutical industry. How much of that focused on
17 health insurance issues?

18 **A.** Almost all of it.

19 **Q.** Dr. Hughes, let's turn to another part of your
20 professional work. Do you also serve as an expert witness
21 from time to time?

22 **A.** I do.

23 **Q.** And approximately how many cases have you testified as
24 an expert over the course of your career?

25 **A.** It's somewhere between 30 and 40 over 25 years.

1 Q. And have those cases focused on matters involving the
2 pharmaceutical industry and insurance matters?

3 A. Yes, almost all of them.

4 Q. And in addition to those cases, have you also been
5 asked to offer opinions in several other opioid litigation
6 matters?

7 A. I have. I've been asked to offer opinions in the Ohio
8 case, here in West Virginia, the State of Washington, and
9 the State of Rhode Island.

10 Q. Are you being compensated for your work in this case?

11 A. I am.

12 Q. And what is your hourly rate?

13 A. My hourly rate is \$950 an hour.

14 Q. How long have you been working on this case involving
15 the City of Huntington and Cabell County?

16 A. I began work in July of 2020.

17 Q. And what tasks have you worked on since you started
18 working on this project? What have you, what have you done
19 to pursue this project?

20 A. Sure. I have researched the, the situation, the
21 insurance situation in West Virginia, reviewed documents,
22 reviewed the record in the case, deposition testimony, and
23 some of the documents that have been produced.

24 Q. Now, did you perform any original analyses of insurance
25 claims data as part of your work in the case?

1 **A.** No, I have not.

2 **Q.** And why not?

3 **A.** Well, first of all, I -- it wasn't really within the
4 scope of my assignment. But, secondly, I don't believe it
5 was necessary to reach the conclusions that I did.

6 The record has much information. There's a lot of
7 public, publicly available reports. And these were adequate
8 to demonstrate that the tools that I discussed were
9 available and usable and effective.

10 **Q.** Did you receive help from support staff in performing
11 your work in this case?

12 **A.** Yes. I was, I was assisted by the staff at Cornerstone
13 Research.

14 **Q.** And what is Cornerstone Research?

15 **A.** Cornerstone Research is a -- I would call it a
16 multi-faceted consulting firm.

17 **Q.** And what is your relationship with Cornerstone?

18 **A.** I've worked with Cornerstone for about 10 years on
19 various matters.

20 **Q.** So, Dr. Hughes, we've talked about your involvement in
21 teaching and academic research, expert witness matters and
22 research. Through all of those different areas of your
23 professional life, have you had a real focus on health
24 insurance matters related to the pharmaceutical industry?

25 **A.** Yes, I believe I would characterize it that way.

1 **Q.** And have you developed a specific expertise in health
2 insurance matters and economics of health insurance as they
3 relate to the pharmaceutical industry?

4 **A.** Health insurance and the pharmaceutical distribution
5 system, yes, I believe I have.

6 **Q.** And how long have you been focused in this area?

7 **A.** About 25 years.

8 MR. HESTER: Your Honor, I now tender the witness
9 as an expert in health economics and health insurance
10 related to prescription medicines.

11 THE COURT: Any objection?

12 MR. MAJESTRO: No, Your Honor.

13 BY MR. HESTER:

14 **Q.** Dr. Hughes, before we get into your opinions --

15 THE COURT: Let me --

16 MR. HESTER: Oh, I'm sorry, Your Honor. Sorry. I
17 was on a roll.

18 THE COURT: I find that Dr. Hughes is an expert in
19 the area of health economics and health insurance -- how did
20 you phrase it?

21 MR. HESTER: Yes. I said, Your Honor, an expert
22 in health economics and health insurance related to
23 prescription medicines.

24 THE COURT: I find him to be an expert in those
25 fields. You may proceed.

1 MR. HESTER: Thank you, Your Honor.

2 BY MR. HESTER:

3 Q. Dr. Hughes, before we get into your opinions, I'd
4 like to cover some of the topics that you're not
5 addressing in your opinions today.

6 Have you been asked to determine or apportion causation
7 in this matter?

8 A. I have not.

9 Q. Are you offering any opinions related to an assignment
10 of fault or blame to any parties?

11 A. No.

12 Q. And are you offering an evaluation of any subject
13 outside of health insurance and how health insurance affects
14 the prescribing of opioids?

15 A. I am not.

16 Q. All right. So now, Dr. Hughes, let's begin by talking
17 a little bit about the various participants in the market
18 for prescription pharmaceuticals. And I'd like to focus on
19 the role of payers. You mentioned payers before and I'd
20 like to focus on the role of payers and how prescription
21 medicines go to patients with the assistance of payers.

22 So we'll put up a schematic here.

23 So, Dr. Hughes, is this a schematic that you prepared
24 as part of your expert report to explain the way this
25 industry works?

1 **A.** Yes, it is.

2 **Q.** And over on the left-hand side we see a familiar set of
3 terminologies; a manufacturer, distributor, pharmacy,
4 patient. Do you see that?

5 **A.** I do.

6 **Q.** And then could you describe generally what, what you
7 have over here? You have pharmacy benefit managers, health
8 insurers, and plan sponsors.

9 What, what are those parties and what do they signify
10 in terms of the way this industry works?

11 **A.** If we start in the lower right-hand corner, we have
12 listed West Virginia Medicaid, PEIA, and other plan
13 sponsors.

14 Plan sponsors are entities that organize and provide
15 healthcare to their beneficiaries or employers -- excuse
16 me -- employees.

17 So, typically, plan sponsors tend to be employers,
18 union benefit plans. And they also can include government
19 agencies like Medicare and Medicaid.

20 If we move up to health insurer managed care
21 organization, this refers to -- largely refers to the type
22 of insurance companies that you're used to hearing, Aetna,
23 United Healthcare, and the like. And these are
24 organizations that sell in various forms health insurance
25 services to the plan sponsors and the beneficiaries of the

1 plan sponsors.

2 **Q.** So let me stop you there for just a second, Dr. Hughes,
3 so we make sure we cover all these points.

4 So you mentioned this plan sponsors which are down here
5 in the lower corner. Is the State of West Virginia a plan
6 sponsor?

7 **A.** Yes, through the West Virginia -- excuse me -- West
8 Virginia Medicaid and the PEIA.

9 **Q.** And what is the role of the state in administering
10 Medicaid?

11 **A.** Medicaid is a joint federal and state health insurance
12 program for low income individuals. Each state has somewhat
13 different regulations that govern Medicaid. And each state
14 governs its own Medicaid program in compliance with federal
15 rules that basically dictate the minimum benefits that have
16 to be included in every plan.

17 **Q.** And you also list on this diagram PEIA. Is that the
18 Public Employees Insurance Agency?

19 **A.** It is, yes.

20 **Q.** And what is the PEIA?

21 **A.** PEIA is an organization that provides health insurance
22 to public employees and some school districts in West
23 Virginia.

24 **Q.** So the diagram, in addition to these plan sponsors,
25 lists health insurers. How are health insurers different

1 from plan sponsors?

2 **A.** Health insurers are the companies that actually
3 organize and sell the healthcare services that -- where you
4 purchase health insurance from.

5 **Q.** And then the diagram also lists pharmacy benefit
6 managers. What are they?

7 **A.** Pharmacy benefit managers are companies that, as the
8 name implies, they administer the pharmacy benefits for the
9 health insurance and plan sponsor organizations.

10 Primarily, they adjudicate pharmacy claims and pay the
11 pharmacy and bill the health insurer. But over time they've
12 also expanded into other ancillary services that they
13 provide in the industry.

14 **Q.** So these three types of entities that we've been
15 discussing, plan sponsors, health insurers, and pharmacy
16 benefit managers, collectively is that what we refer to as
17 payers?

18 **A.** Yes, it is.

19 **Q.** Dr. Hughes, in connection with your work on this
20 matter, did you review data on the percent of people in West
21 Virginia who are covered by health insurance?

22 **A.** Yes, I have.

23 **Q.** And what was the source of that data?

24 **A.** The source of that data was a Kaiser Family Foundation
25 document on health insurance coverage by payer by state.

1 Q. And what is the Kaiser Family Foundation data based
2 upon?

3 A. The Kaiser -- this Kaiser Family Foundation study was
4 based on data from the U.S. Census Bureau as contained in
5 the American Community Survey which is run every year by the
6 Census Bureau.

7 Q. And did you rely on this Kaiser Family Foundation data
8 in forming your opinions in this case?

9 A. I did.

10 Q. And is this the type of data that you would rely upon
11 as a health economist, broadly speaking?

12 A. Yes.

13 Q. And do you consider it a reliable source of
14 information?

15 A. Yes. The Kaiser Family Foundation information is
16 commonly used by economic and other researchers in the
17 health field.

18 Q. Have you prepared a demonstrative based on the Kaiser
19 Family Foundation data to show --

20 A. Yes.

21 Q. -- the coverage rates in West Virginia for people who
22 are, have coverage for health insurance?

23 A. Yes. Sorry. Yes, I have.

24 Q. All right. So, Dr. Hughes, what does this
25 demonstrative show at a high level? What's it purporting to

1 show?

2 **A.** Well, at a high level, it shows the total number -- on
3 the far right-hand side in the top row, it shows the total
4 number of people who are insured in West Virginia, which is
5 about 1.6 million. And --

6 **Q.** In 2018?

7 **A.** Yes, I'm sorry, in 2018. And going across the top row,
8 it shows about 773,000 have employer insurance. 55,000 have
9 individual or non-group insurance. And that would largely
10 be people getting insurance through the healthcare,
11 marketplace of the Affordable Care Act. 463,000 in
12 Medicaid; 329,000 in Medicare; 22,000 in military; and
13 108,000 individuals are uninsured.

14 **Q.** And what does this data reflect about the percentage of
15 people in West Virginia who have health insurance?

16 **A.** Overall, about 94 percent of people in West Virginia
17 have health insurance.

18 **Q.** And could you also provide us with a percentage of --
19 what percentage of people are insured under health employer
20 sponsored plans?

21 **A.** Just under half, about 44 percent under employer health
22 insurance plans.

23 **Q.** And what percentage are covered by West Virginia
24 Medicaid?

25 **A.** That's 26 percent.

1 Q. And what percentage are covered by Medicare?

2 A. About 19 percent.

3 Q. And the remaining are covered by health insurance
4 directly from an insurance company or through the military?

5 A. That's correct.

6 Q. With about 6.2 percent of the population of West
7 Virginia being unemployed -- I'm sorry -- uninsured?

8 A. Correct.

9 Q. Would you expect the Medicaid percentage that we show
10 here, 26 percent, would you expect that Medicaid percentage
11 to be about the same for Cabell and Huntington?

12 A. No. I would expect the percentage to be higher in
13 Cabell County and Huntington.

14 Q. At the percentage of people covered by Medicaid?

15 A. Yes, the percentage of people covered by Medicaid. I
16 would expect that to be higher in Cabell County and
17 Huntington.

18 Q. And why would you expect that?

19 A. Well, the primary qualification for Medicaid is one's
20 level of income. And the income level in Cabell County is
21 substantially below the statewide average. So I would
22 expect the Medicaid percentage to be somewhat above the
23 statewide average for Medicaid coverage.

24 Q. Would you expect to see any difference in Cabell County
25 and the City of Huntington with respect to the percentage of

1 people who are insured by some health insurance?

2 **A.** No. I would expect that to be about the same,
3 especially by 2018 with the Medicaid -- yes, excuse me --
4 with the Medicaid expansion under the Affordable Care Act.

5 **Q.** What is the income eligibility requirement for
6 Medicaid?

7 **A.** The basic eligibility requirement is you have to earn
8 less than 138 percent of the federal poverty level.

9 **Q.** And do you know roughly what percentage of the Cabell
10 County population is below the poverty level?

11 **A.** I understand that -- I understand that it's said to be
12 about 30 percent of the population of Cabell County is below
13 the poverty level.

14 **Q.** Is that based on testimony from Mayor Williams?

15 **A.** Yes. I couldn't remember his name. Thank you.

16 **Q.** And would you expect -- if, if roughly 30 percent of
17 Cabell County and the City of Huntington population is below
18 the poverty line, would you expect even more people than
19 that would fall within the 138 percent eligibility
20 requirement for Medicaid?

21 **A.** Yes. I mean, I think it's safe to conclude that in
22 Cabell County, 30 percent or more of the population would at
23 least be eligible for Medicaid. Whether or not they
24 actually sign up for it is another question.

25 **Q.** Did you review data as well, Dr. Hughes, on the retail

1 prescription drugs that are filled at pharmacies and are
2 subject to some sort of insurance reimbursement?

3 **A.** Yes, I have.

4 **Q.** And what was the source of that data?

5 **A.** That is another Kaiser Family Foundation document, this
6 one on prescription, prescription payment by payer type.

7 **Q.** And is that a document you also relied on in forming
8 your opinions in this case?

9 **A.** Yes, it was.

10 **Q.** And the type of data that you would generally rely on
11 as a health economist?

12 **A.** Yes.

13 **Q.** And do you consider the Kaiser Family Foundation data
14 on insurance coverage for prescription drugs to be a
15 reliable source of information?

16 **A.** Yes, in this case, yes.

17 **Q.** Did you prepare a demonstrative based on that data to
18 aid your testimony?

19 **A.** I did indeed.

20 **Q.** So, Dr. Hughes, what does this demonstrative show at a
21 high level?

22 **A.** Again, in 2019, this shows the reimbursement rate for
23 prescriptions by type of payer, commercial insurance,
24 Medicare, Medicaid, and cash payers.

25 **Q.** And when you refer to reimbursement rates, what do you

1 mean by that?

2 **A.** A reimbursement rate is the -- in this case, the
3 fraction of payments for prescriptions by insurers. So we
4 refer to -- when my insurance company pays for my
5 prescription, it's referred to as reimbursed for that
6 prescription.

7 **Q.** So let's focus on the percentage line here, the
8 percentage of, of prescriptions covered by the different
9 forms of insurance. Could you just state what you're seeing
10 here on this demonstrative?

11 **A.** Sure. Commercial insurance, about 41 percent of
12 prescriptions were covered by commercial insurance;
13 Medicare, about 29 percent; Medicaid, about 25 percent; and
14 only about 4 percent were paid in cash.

15 THE COURT: What if there's a co-pay? Did you
16 figure that in?

17 THE WITNESS: This doesn't have to do with
18 dollars, Your Honor. This just is the count of
19 prescriptions.

20 THE COURT: Oh, okay.

21 BY MR. HESTER:

22 **Q.** So does this tell us, Dr. Hughes, what percentage
23 of the prescriptions in West Virginia for all drugs,
24 what percentage of the prescriptions are covered by
25 insurance?

1 **A.** Yes.

2 **Q.** And what's that percentage?

3 **A.** That percentage is about 96 percent.

4 **Q.** And about 4 percent of prescriptions in West Virginia
5 are paid for in cash?

6 **A.** That's correct.

7 **Q.** Now, this is, this is covering all prescription drugs
8 in West Virginia; correct?

9 **A.** That's correct.

10 **Q.** Would you expect a breakdown in terms of insurance
11 coverage to be the same for prescription opioids?

12 **A.** No, I would not.

13 **Q.** What would you expect the difference to be?

14 **A.** I would expect a higher fraction of the opioid
15 prescriptions would be paid for by Medicaid.

16 **Q.** And would you expect the total percentage of
17 prescriptions covered by some form of insurance to be the
18 same; in other words, about 96 percent of prescription
19 opioid prescriptions would be covered by insurance?

20 **A.** Yes, I would think so.

21 **Q.** And why is that, Dr. Hughes?

22 **A.** There were two things in there. I'm sorry. Why is
23 what?

24 **Q.** I'm sorry. Why, why would you expect that the
25 percentage coverage for insurance for prescription opioids

1 would be comparable to the percentage coverage for all
2 prescriptions?

3 **A.** Yes. Again, because of the Medicaid expansion under
4 the Affordable Care Act, we saw before that almost all West
5 Virginians are covered by some sort of insurance. And, so,
6 they would also have prescription drug coverage that would
7 go along with that.

8 **Q.** So your understanding would be roughly speaking
9 something in the range of 96 percent of prescription opioids
10 dispensed in West Virginia would be covered by some form of
11 insurance?

12 **A.** I would think so, in the mid 90 percentile, yeah.

13 **Q.** Let's talk a little bit about the incentives of payers.
14 Are payers only willing to reimburse for prescriptions that
15 are medically necessary?

16 **A.** Yes, that's -- I believe that's correct.

17 **Q.** And why is that?

18 **A.** To pay for medically unnecessary prescriptions is, in
19 effect, a waste of money. The insurer is paying for a
20 prescription that does not yield a commensurate medical
21 benefit to the patient.

22 And, so, that raises the cost of the insurance company.
23 And it's a cost that they have to recover through higher
24 premiums charged to beneficiaries and to plan sponsors.

25 **Q.** Is there also a policy requirement under West Virginia

1 Medicaid about paying only for medically necessary services?

2 **A.** Yes. West Virginia Medicaid has a written policy that
3 it will cover only medically necessary health services.

4 **Q.** Now, you've been speaking generally about medically
5 necessary health services. Would that same point apply to
6 reimbursement by insurers of prescription opioids?

7 **A.** Yes, I believe it would.

8 **Q.** And, so, what does that mean in terms of the payers'
9 reimbursement practices? Let me strike that and start over.

10 What does this point mean about insurers looking at
11 medically necessary services? What would that mean about
12 their reimbursement practices with respect to prescription
13 opioids?

14 **A.** It means that they have incentive to use tools at their
15 disposal in order to determine and make sure that the
16 prescriptions that are reimbursed are, in fact, medically
17 necessary.

18 **Q.** And would insurers be looking, therefore, at the
19 medical necessity of a prescription in evaluating whether
20 they would reimburse for it?

21 **A.** Yes.

22 **Q.** And would they also be looking at the number of pills
23 included in a prescription in evaluating whether it was
24 medically necessary and appropriate to reimburse?

25 **A.** Yes. They only want to reimburse for the number of

1 pills necessary to treat the patient's condition.

2 **Q.** So how do payers determine whether a particular
3 prescription or a whole wide range of prescriptions are
4 medically necessary and appropriate? How do they do that?

5 **A.** Well, one of the ways they do it is through a practice
6 known as prior authorization through which the physician
7 when prescribing a particular drug has to provide an
8 explanation and justification for that, prescribing that
9 drug based on the patient's condition, the patient's medical
10 history, their co-morbidities and the like.

11 **Q.** Do payers also have doctors on staff who are engaged in
12 the process of evaluating medical necessity if there are
13 reimbursements?

14 **A.** Yes. The medical insurers have formulary committees
15 that are tasked with deciding what drugs are going to be
16 covered and at what level. Those panels have physicians on
17 board that bring the current state of medical knowledge and
18 the current best practice into the discussion.

19 And, also, physicians are involved in insurer's drug
20 utilization reviews which are data based reviews that are
21 conducted to, again, try to make sure that they are
22 reimbursing only those prescriptions that are medically
23 necessary.

24 **Q.** So how, how are payers' practices in evaluating medical
25 necessity of reimbursement for prescription opioids or any

1 other prescription drug, how are those practices affected by
2 evolving standards of care?

3 **A.** Well, that's the role of the doctors on formulary
4 committees and on drug utilization reviews. As time goes on
5 and more knowledge is gained about particular drugs or more
6 knowledge is gained about the, the medical results of
7 prescribing particular drugs, those factors regarding the
8 standard of care come into the discussions on what drugs
9 will be included on the formulary as well as the utilization
10 review which is a retrospective look at how effective
11 particular drugs have been at treating particular ailments.

12 **Q.** So, so is it fair to say that the payers' approach to
13 determine what prescriptions are medically necessary and
14 what they will reimburse will evolve over time as the
15 standard of care evolves? Is that a fair way to put it?

16 **A.** Yes, I believe that's fair.

17 **Q.** By only reimbursing what payers consider to be
18 medically necessary, are the payers purporting to supplant
19 or replace the judgment of doctors?

20 **A.** No, I don't believe so. I believe that the process
21 like prior authorization is basically a chance for the, for
22 two things to happen; for the doctor to reflect on the
23 prescription that he or she is writing to make sure that it
24 fits with the patient's needs and the patient's medical
25 history and other factors, and it's a check on the doctor to

1 make sure that they are either adhering to the standard of
2 care that the payer has set, or if they're not adhering to
3 the standard of care to justify why they're not.

4 But it also bears pointing out that the doctor's
5 medical judgment is unquestioned by payers when the prior --
6 when there's not prior authorization on the drug. Doctors
7 are considered to have determined that prescriptions are
8 medically necessary and the payers generally reimburse these
9 without question.

10 **Q.** And, Dr. Hughes, in your experience over many years of
11 studying this industry, do payers, in fact, perform analyses
12 and employ tools to identify or limit medically unnecessary
13 prescriptions?

14 **A.** Yes, all the time.

15 **Q.** And do payers have processes in place to reject
16 coverage for prescriptions that they deem medically
17 unnecessary?

18 **A.** Exactly. So prior authorization is one way to do this.
19 And failure to adhere to, say, step therapy is another
20 reason to reject a prescription.

21 **Q.** So when a payer reimburses for a prescription, does
22 that fact indicate that the payer concluded that the
23 reimbursed prescription was medically necessary?

24 **A.** Yes, I believe that's true.

25 **Q.** And would that same point apply to reimbursement for

1 prescription opioids?

2 **A.** Yes.

3 **Q.** So, Dr. Hughes, now let's pivot a little bit and talk
4 about information flows. Let's go back to this
5 demonstrative.

6 So we talked about plan sponsors. We talked about
7 health insurance, pharmacy benefit managers. Let's talk
8 about the information that payers have about a particular
9 prescription and let's -- so, Dr. Hughes, we've now put some
10 lines up on this board reflecting information.

11 Could you describe what that is reflecting?

12 **A.** Sure. A primary source of information to the payers is
13 the claims information that comes from the pharmacy. It
14 flows generally initially to the pharmacy benefits manager
15 or to the health insurer depending on basically the terms of
16 the contract.

17 Claims information also flows from pharmacy benefit
18 managers to the health insurers. And that can be in the
19 form of raw claims information or one of the ancillary
20 services I was talking about before.

21 Pharmacy benefit managers can and do perform various
22 analyses on behalf of the insurers. And, so, they may get
23 claims information that has already been processed in some
24 way or to answer a particular question that the health
25 insurer asks.

1 From the patient, the patient gives the physician
2 medical information. The physician passes on through the
3 doctor's claim to the health insurer, passes on that medical
4 information to the health insurance organization. And the
5 health insurer passes on utilization information,
6 utilization reviews back to the payers.

7 **Q.** So the claims data that the payers would receive
8 includes information about the patient, the prescriber, and
9 the service or the prescription provided; is that correct?

10 **A.** The claims information would contain a lot of different
11 details. So it would include information on the provider,
12 the patient, the pharmacy, the drug, the dosage of the drug,
13 the number of the pills. And it would also be available how
14 many prescriptions for how many different drugs the patient
15 might also be taking.

16 **Q.** And, so, how is it that the payers obtain this
17 information?

18 **A.** When the claim is adjudicated when the pharmacy turns
19 it into the pharmacy benefits manager to be reimbursed for
20 the prescription that they've dispensed, they transmit this
21 claims information electronically to the pharmacy benefits
22 manager who then turns it over either again in the raw form
23 or in processed form to health insurers and to payers.

24 **Q.** So do payers collect this kind of individual data for
25 every claim they process?

1 **A.** They do.

2 **Q.** And would that include every claim they process for the
3 reimbursement of a prescription opioid?

4 **A.** It would.

5 **Q.** Do payers have the ability to analyze the prescribing
6 and prescription trends using that kind of claims data?

7 **A.** Yes, they have that ability and they, they make use of
8 that ability.

9 **Q.** And I wanted to ask you in your experience studying
10 this industry over a long time, have you seen evidence that,
11 in fact, payers do undertake that kind of analysis of claims
12 data as it arrives?

13 **A.** Yes. It is an on-going -- major insurers, major payers
14 will either have in-house data capabilities or they have
15 vendors that they go to that process and provide analyses of
16 particular questions that the payer puts them in.

17 **Q.** So, so can payers use the claims data they receive to
18 identify trends and the number of, let's say, prescription
19 opioid prescriptions that they paid for that were written by
20 particular doctors?

21 **A.** Yes, they could.

22 **Q.** Could they use that kind of claims data on prescription
23 opioids to analyze individuals who are receiving particular
24 prescriptions for opioids?

25 **A.** Yes, they could do that as well.

1 Q. Could they undertake as well to evaluate the opioids
2 that they're reimbursing of particular pharmacies?

3 A. Yes, they could do it at the pharmacy level as well.

4 Q. Would payers have the ability to identify patients who
5 are receiving high volumes of prescription opioids?

6 A. Yes, the prescriptions that they've reimbursed, yes.

7 Q. And would they also have the ability to evaluate
8 doctors who are writing high volumes of prescriptions?

9 A. Yes, they would.

10 Q. And have you reviewed examples that are consistent with
11 these kinds of analyses, that payers analyze claims data in
12 these ways to look at patients, to look at doctors, to look
13 at individual pharmacies?

14 A. Yes, I have.

15 Q. I wanted to focus particularly on two specific payers
16 that we've already talked about a little bit, West Virginia
17 Medicaid and the Public Employees Insurance Agency.

18 Have you reviewed the deposition testimony of
19 individuals involved in administering those health plans?

20 A. I have.

21 Q. And have you reviewed documents related to those health
22 plans?

23 A. I have.

24 Q. And based on your review of the deposition testimony
25 and documents, do you have an opinion as to whether West

1 Virginia Medicaid and the Public Employees Insurance Agency
2 were performing these kinds of analyses that we've just
3 discussed in relation to different prescriptions?

4 **A.** Yes. I did examine that and they are performing the
5 types of analyses that we just discussed previously.

6 **Q.** And would you expect private payers to be engaging in
7 the same kind of analyses of the prescriptions that they
8 reimburse?

9 **A.** I know they are, yes.

10 **Q.** Do the claims data and the, and the ability to analyze
11 information, the kind of information that's shown on the
12 board here, does that apply only to prescriptions that the
13 payers reimburse?

14 **A.** Yes. If the -- if a prescription is reimbursed by a
15 different payer or if a prescription is paid in cash, that
16 payer would not -- it would be -- it's not impossible, but
17 it would be unlikely that the payer would get claims
18 information on that.

19 **Q.** Is there another database that contains information
20 about all opioids dispensed in the State of West Virginia?

21 **A.** Yes. Since 2004, I believe, West Virginia has run the
22 Controlled Substance Monitoring Program which collects data
23 on every opioid prescription dispensed in West Virginia.

24 **Q.** And can the CSMP be used to perform all of the analyses
25 for controlled substances prescribing that we've just been

1 discussing in relation to claims data?

2 **A.** Yes. And the Bureau of Pharmacy presents annual
3 reports that contain many of the types of analyses that we
4 just discussed.

5 **Q.** And, Dr. Hughes, are you aware as to when West Virginia
6 mandated that doctors use the CSMP before writing opioid
7 prescriptions?

8 **A.** I believe that was in 2019.

9 **Q.** Does West Virginia Medicaid have access to the CSMP?

10 **A.** They do on a patient by patient basis.

11 **Q.** Can anyone else access the CSMP if they want?

12 **A.** Not anyone else. There is -- in the law that
13 established the CSMP and as it's been amended, there's a
14 list of types of organizations and individuals who are able
15 to access the CSMP.

16 **Q.** Do distributors have access to the CSMP?

17 **A.** No, they do not.

18 **Q.** Does PEIA have access to the CSMP? And PEIA again is
19 the Public Employees Insurance Agency. Does that have
20 access to the CSMP?

21 **A.** They do not. As a state organization, they could
22 petition for such access but they, they do not currently
23 have access.

24 **Q.** All right. So, Dr. Hughes, we've been talking so far
25 about information flows and the information available to

1 payers through claims data and the like.

2 Let's also talk about tools that are available to
3 payers that would allow them to influence opioid
4 prescribing.

5 And before we do that, I wanted to clarify that the
6 claims information we've been talking about, these are flows
7 of information that would apply to any kind of prescription,
8 so that would include prescription opioids that are being
9 reimbursed by insurers; correct?

10 **A.** That's correct, yes.

11 **Q.** So now let's talk about tools that are available in
12 order to influence opioid prescribing or prescribing of
13 other drugs.

14 So now, Dr. Hughes, we've put another set of lines --

15 MR. HESTER: Your Honor, I promise this is the
16 last set of lines we'll put up.

17 THE WITNESS: I'm sorry.

18 BY MR. HESTER:

19 **Q.** And we've put up some more lines. Could you
20 describe what these red lines are meant to show on this
21 diagram?

22 **A.** Sure. The general term "prescription management tools"
23 refers to how the health insurers and the pharmacy benefit
24 managers leverage this claims information that they receive
25 into tools that can be used to affect the prescribing of

1 opioids or any other drug that -- whose prescribing they
2 wish to modify.

3 **Q.** So is it fair to say, Dr. Hughes, that information on
4 claims is coming into this group of payers? Is that fair?

5 **A.** That's true, yes.

6 **Q.** And then the payers have tools available to them to
7 respond to that information flow and try to exercise control
8 over the way that prescribing activity takes place? Is that
9 fair?

10 **A.** Yeah, exactly. They make use of that information in
11 devising appropriate tools for modifying prescriber behavior
12 primarily.

13 **Q.** So, Dr. Hughes, let's talk about some examples of some
14 tools that payers have at their disposal to influence
15 prescribing behavior.

16 So I've written up on the board "tools to influence
17 prescribing." Are there some good examples you would offer
18 of tools that are available to payers that can influence
19 prescribing behavior?

20 **A.** Yes. There are three that I think are the strongest
21 tools. And those are prior authorization. Secondly would
22 be step therapy. And thirdly would be quantity limits.

23 **Q.** Are those tools that only payers can use to influence
24 prescribing behavior?

25 **A.** That's correct.

1 **Q.** Why is that?

2 **A.** They are the ones who decide the rules on what is going
3 to be reimbursed and what's not going to be reimbursed.

4 **Q.** Why did you pick these three examples that I've listed
5 up here on the board? Why did you pick those three as the
6 examples of tools that are available to influence
7 prescribing behavior?

8 **A.** Well, short of choosing not to cover a particular drug
9 at all, these are the -- I believe the three strongest tools
10 that are available to effect prescriber prescribing
11 behavior.

12 **Q.** So let's go through these one at a time quickly.
13 What is prior authorization?

14 **A.** Prior authorization, we're already talked about that a
15 little. It's a procedure that's used widely for
16 prescription drugs. And it is a system where the doctor is
17 required to provide a fact-based explanation or
18 justification for prescribing one drug over another.

19 And that gives the payer the opportunity to review the
20 doctor's explanation and decide whether they agree that the
21 prescription is medically necessary or to decide that the
22 prescription is not medically necessary.

23 **Q.** And what happens if the doctor does not get prior
24 authorization?

25 **A.** Then the prescription would not be reimbursed by the

1 payer.

2 **Q.** And how can payers use prior authorization to encourage
3 limits on the amount of opioids prescribed?

4 **A.** Well, there's really two ways. I mean, first of all,
5 the process of having to explain the rationale based on the
6 patient's condition, the patient's medical history, the
7 patient's age, overall health, the exercise of having to
8 explain that in the course of writing a prescription gives
9 the doctor the opportunity to reflect on a particular
10 prescription and to decide whether the drug is appropriate,
11 the dosage is appropriate, the number of pills is
12 appropriate. So the hope is that the doctors are, are
13 providing a thoughtful explanation and justification.

14 The second way is, of course, if there are drugs that
15 are on prior authorization and drugs in the same therapeutic
16 class that aren't on prior authorization, or drugs that
17 accomplish the same goal that are not on prior
18 authorization, the doctor may simply choose not to take the
19 time to complete the prior authorization form and switch
20 from an opioid to some other prescription drug.

21 **Q.** So just to clarify or expand on that point --

22 **A.** Uh-huh.

23 **Q.** -- could there be a situation where an opioid is on
24 prior authorization and some other alternative pain
25 treatment is not on prior authorization, so the doctor might

1 be incentivized to pick the drug that's not subject to prior
2 authorization? Is that your point?

3 **A.** Yes. They may just not want to engage in the prior
4 authorization exercise and just prescribe something else
5 that would not require prior authorization.

6 **Q.** What is step therapy, the second point you raised?

7 **A.** Step therapy is a tool by which a patient -- let's take
8 a -- take an example. Suppose a doctor wishes to prescribe
9 a brand name opioid. A step therapy program might require
10 that before that brand name opioid would be approved to be
11 prescribed that the patient has to be tried on perhaps an
12 alternative therapy like physical therapy or a non-opioid
13 medication and demonstrate that the treatment has failed.
14 And only after the treatment has failed would they be
15 willing to reimburse the -- in this case, the brand name
16 opioid.

17 **Q.** So how can payers use step therapy to encourage limits
18 on the amount of opioid prescribing?

19 **A.** Well, hopefully if the initial non-opioid therapy is
20 successful in treating the patient's pain, then that's one
21 less opioid prescription that is written.

22 **Q.** What are quantity limits? That's the last of the three
23 we discussed.

24 **A.** Yeah, that's very basic. It's just simply saying
25 that -- the insurer is saying we will not reimburse for more

1 than X number of pills. So maybe in a month we will only
2 reimburse for 30 or 60 pills. And you have to -- basically
3 would have to go through prior authorization if the doctor
4 wanted to prescribe more.

5 **Q.** So to perhaps state the obvious, how would that
6 encourage limits on the amount of opioid prescribing?

7 **A.** I think the easiest way to think of it to the extent
8 that it's effective, quantity limits can reduce the average
9 number of pills in an opioid prescription. And through
10 reducing that average number of pills per prescription,
11 fewer opioids are out in the world.

12 **Q.** Have you reviewed literature regarding the
13 effectiveness of these kinds of tools for affecting
14 prescribing behavior?

15 **A.** I have.

16 **Q.** And can you provide an example of that?

17 **A.** Yes. There was a -- what's called a mega analysis of
18 15 different studies on prior authorization. And it was
19 concluded that prior authorization reduces the prescribing
20 of the target drug by an average of about 52 percent.

21 **Q.** Have experts recognized that these tools can be used
22 effectively to encourage limits on prescribing of opioids in
23 particular?

24 **A.** Yes. There have been studies, academic studies as well
25 as government reports and government task force, that have

1 emphasized that these types of tools can be effective in
2 reducing the prescribing of opioids.

3 **Q.** Now, we've been talking about these tools to limit
4 prescribing behavior. And, of course, that's imposed by
5 insurers. Would this also have an impact on prescribing for
6 patients who don't have insurance?

7 **A.** Yes. Research has shown that to the extent that
8 prescribers' behavior for insurance companies, for patients
9 that have insurance, to the extent that they alter their
10 prescribing behavior, they also follow the same changes when
11 treating patients without insurance.

12 So even if a patient doesn't have insurance, use of
13 these tools may well affect the type of product that a
14 doctor would prescribe for uninsured patients.

15 **Q.** Now, are these prescription management tools like prior
16 authorization, step therapy, or quantity limits meant to
17 supplant the judgments of prescribers?

18 **A.** No, it's not intended at all to replace the judgment of
19 prescribers. And, again, if there's -- if these are not
20 used, then -- which is also quite common in pharmaceuticals,
21 where these tools are not used, the insurance company is
22 relying completely on the doctor's judgment that a
23 prescription is medically necessary and they fill the --
24 excuse me -- they reimburse for the prescription without any
25 question.

1 But the prior authorization and step therapy again is
2 two steps; first of all, to make -- to incentivize the
3 doctor to reflect that their treatment is, indeed,
4 appropriate for the patient and for the payer to assure
5 themselves that the doctor is adhering to whatever standard
6 of care the payer has designated. And if they are not, to
7 explain themselves as to why they're not adhering to that
8 particular standard of care.

9 **Q.** Now, Dr. Hughes, have you undertaken an analysis of
10 whether payers in West Virginia used the prescription
11 management tools that we've just been discussing to limit
12 opioid prescribing?

13 **A.** I have.

14 **Q.** And which payers did you look at for your analysis?

15 **A.** I examined West Virginia Medicaid and the Public
16 Employees Insurance Agency.

17 **Q.** Why did you pick those payers?

18 **A.** As public organizations, they have much publicly
19 available information. And there was also additional
20 information that was produced in the course of this
21 litigation.

22 **Q.** And, roughly, between the two of them, what percentage
23 of the West Virginia population did they insure?

24 **A.** Medicaid is about 26 percent and PEIA I believe is
25 about 14 percent. So it's about 40 percent in total.

1 **Q.** Would you expect other payers, other insurers to behave
2 similarly to what you've observed with the West Virginia
3 Medicaid and the Public Employees Insurance Agency?

4 **A.** Yes. Whether an insurer is a public entity or a
5 private company, they face the same incentives to minimize
6 the cost of providing adequate and effective care.

7 **Q.** So what did you find in your analysis with respect to
8 the use of these prescription management tools?

9 **A.** I found that early on, meaning in the early part of the
10 21st Century, Medicaid and PEIA made use of these tools, but
11 really only made use of these tools in ways that were
12 designed to control costs as opposed to promote any
13 particular clinical outcome.

14 **Q.** And when you say promote any clinical outcome, what do
15 you mean by that?

16 **A.** I mean taking into account the risk benefit balance
17 that has to be made with controlled substances like opioids,
18 taking that into account in devising their prior
19 authorization or step therapy or quantity limit rule.

20 **Q.** Did you see evidence that in more recent years West
21 Virginia Medicaid and the Public Employees Insurance Agency
22 have, in fact, undertaken prescription management tools to
23 achieve clinical outcomes as you've described?

24 **A.** Yes. And especially in the post-2016 period, both
25 organizations took steps that indicate that they were making

1 use of these tools in response to clinical concerns in
2 addition to cost control.

3 **Q.** And let's give the Court an example of what you found.
4 Let's first talk about quantity limits.

5 When did West Virginia Medicaid first impose quantity
6 limits for the class of opioid prescriptions? And if it
7 would help you, Dr. Hughes, if it helps refresh your
8 recollection, we can provide your report to you.

9 **A.** No. Quantity limits, I believe they were -- excuse me.
10 I believe quantity limits were first used around 2005.

11 **Q.** And when did West Virginia Medicaid implement quantity
12 limits for short-acting opioids in particular?

13 **A.** That was 2009.

14 **Q.** And what about dosage quantity limits?

15 **A.** The -- sorry. Excuse my faulty memory. The 2009
16 quantity limits were strictly counts of pills. 120 pills
17 for a thirty-day period was the, was the quantity limit.
18 That had nothing to do with dosage.

19 And then later in the 2015-2016 period, they began to
20 impose quantity limits, for example, for opioid therapy that
21 was going to extend longer than 90 days; that the prescriber
22 could only prescribe 50 MME per day for such therapy. And
23 if they wanted to exceed that dosage, they had to obtain
24 prior authorization.

25 **Q.** So you mentioned these quantity limits, one imposed in

1 2009, one imposed around 2015-2016. Is there any reason
2 that West Virginia Medicaid could not have imposed those
3 quantity limits earlier if it had so chosen?

4 **A.** No, there's no reason.

5 **Q.** Let's talk about step therapy requirements. Did
6 Medicaid implement a step therapy requirement for
7 prescription opioids?

8 **A.** Yes, they did.

9 **Q.** And what's the first example of that that you saw?

10 **A.** That is about 2005. But the step therapy then was
11 designed almost exclusively to incentivize patients to
12 use -- excuse me -- to incentivize providers to prescribe
13 generic opioids rather than branded opioids.

14 So the step therapy was basically you had to initiate
15 the patient on, say, two generic opioids. And they had to
16 be shown to be ineffective for the patient before they would
17 approve the branded opioid.

18 But that use of the tool is, you know, strictly for
19 cost control because in either event, it was an opioid that
20 was to be prescribed.

21 **Q.** And was there a later period when West Virginia
22 Medicaid required step therapy with a focus more on clinical
23 outcomes?

24 **A.** Right. Well, following the, the 2015-2016 change, they
25 changed the step therapy to where before -- now, remember,

1 we had the prior authorization was required if you wanted to
2 exceed 50 MME a day for a long-term opioid therapy.

3 Before the doctor would be allowed to even submit that
4 prior authorization, now the patient had to be initiated on
5 a non-opioid therapy like, say, physical therapy. And that
6 had to be shown to be ineffective before the doctor would
7 even be allowed to petition for -- petition with prior
8 authorization for a higher dosage.

9 **Q.** Let's talk about the Public Employees Insurance Agency.
10 Did you prepare a demonstrative to aid in your testimony to
11 illustrate its use of step therapy and quantity limits?

12 **A.** I did.

13 **Q.** All right. Let's put that up on the board.

14 So, Dr. Hughes, is this a, is this a demonstrative
15 exhibit you prepared?

16 **A.** It is.

17 **Q.** And what does this graph show?

18 **A.** This graph shows the percentage of opioids that
19 required step therapy or quantity limits under PEIA's PDL,
20 which stands for preferred drug list.

21 **Q.** So let's focus first on the requirement for step
22 therapy. What -- now, let me go first to quantity limits.
23 What happened with quantity limits under their insurance
24 program?

25 **A.** Basically, prior to 2016, only about, somewhat less

1 than 40 percent of the opioids on their preferred drug list
2 required quantity limits. And then after 2016 is when it
3 went from less than 40 percent to where 100 percent or every
4 single opioid on their PDL was subject to quantity limits.

5 **Q.** So, again, we're talking about the Public Employees
6 Insurance Agency, or a state insurer; correct?

7 **A.** That's correct.

8 **Q.** And, so, as of 2016, they imposed quantity limits for
9 every prescription opioid that was on their preferred drug
10 list?

11 **A.** That's correct.

12 **Q.** And before that time, it was in the range of 30 to
13 40 percent who were subject to quantity limits?

14 **A.** That's correct.

15 **Q.** Let's talk about what the step therapy requirements
16 were as imposed by PEIA.

17 **A.** Yes. So prior to 2015, there was a relatively small
18 number of opioids on their PDL that was subject to step
19 therapy.

20 In the 2015 to 2020 period, I should say I guess the
21 2015 to 2019 period, no opioids on the PEIA preferred drug
22 list required step therapy.

23 Then in 2020, this jumped from zero up to almost
24 50 percent of the opioids on their preferred drug list would
25 now require step therapy.

1 **Q.** So going back to these quantity limits for a minute,
2 this change where 100 percent of the opioids on their
3 preferred list were subject to quantity limits, do you have
4 an understanding as to what that corresponds with in terms
5 of other developments related to opioids around this time?

6 **A.** Yes. In 2016 the CDC, the --

7 **Q.** Centers for Disease Control?

8 **A.** Thank you. I'm sorry, Your Honor. It's late.

9 THE COURT: It happens to me all the time.

10 THE WITNESS: I'm sorry. Yes. The Centers for
11 Disease Control issued detailed guidelines on opioid use in
12 treating pain. And this -- these were guidelines that many
13 insurers, including PEIA, as well as West Virginia Medicaid,
14 tried to adopt in this time period.

15 BY MR. HESTER:

16 **Q.** So we see this major change in the imposition of
17 quantity limits as of 2016. Without being too specific
18 on the years, would you expect to see other insurers in
19 West Virginia behaving roughly in the same way?

20 **A.** Yes, I would because that -- the CDC report I think
21 would be considered a, a strong statement of what the
22 standard of care should be. And that would have a big
23 influence on not just public insurers, but also private
24 insurers in West Virginia as well as everywhere else.

25 **Q.** So let's talk about prior authorization. Did you

1 prepare a chart on that as well, Dr. Hughes?

2 **A.** I did.

3 **Q.** So, again, this chart is relating to, to Public
4 Employees Insurance Agency and their preferred drug list.
5 And could you describe roughly what it's showing here?

6 **A.** Sure. So in the first column it's the date of the
7 preferred drug list. So preferred drug lists evolve over
8 time as new products come on the market or products turn
9 generic or whatever the case may be. So there is a new one
10 at least every year, sometimes more often.

11 And the second column is the number of opioids on the
12 preferred drug list of the PEIA.

13 And then the third column is the percentage of that
14 number of opioids that does not require prior authorization;
15 that the doctor can write a prescription and the PEIA will
16 reimburse it without question.

17 And the last column is the percentage of -- in 2012
18 those 11 opioids that were subject to prior authorization.

19 **Q.** So let's try to just aggregate this a bit. So if we
20 look up through 2017, roughly speaking, what's the range of
21 opioids that were not subject to prior authorization?

22 **A.** The range is roughly two-thirds to three-quarters of
23 the opioids were not subject to prior authorization.

24 **Q.** And then starting in 2018, what's roughly the range of
25 the opioids that were subject to prior authorization?

1 **A.** After that period, it's basically 85 percent up to
2 100 percent.

3 **Q.** And do you understand that, again, to be linked to the
4 CDC guidelines?

5 **A.** Yes. According to deposition testimony, I recall that
6 they would -- that these organizations were seeking to
7 implement the CDC guidelines.

8 **Q.** Now, we're obviously looking at one large insurer in
9 West Virginia, public insurer. Would you expect other
10 insurers in West Virginia to behave similarly to have begun
11 imposing more prior authorization requirements for opioids
12 in the 2016-2017 period?

13 **A.** Yes. They all faced the, the same constraints and they
14 are all cognizant of the CDC guidelines. So I would expect
15 them to behave similarly. The timing might differ by a year
16 or two, but I would expect them all to be moving in that
17 direction.

18 **Q.** Is there any reason that tools like prior
19 authorization, step therapy, and quantity limits could not
20 have been implemented earlier than they were?

21 **A.** None to my knowledge, no.

22 **Q.** And, Dr. Hughes, do you construe these changes in step,
23 step therapy, prior authorization, quantity limits, does
24 that reflect a change in the standard of care?

25 **A.** Yes. I mean, the, the CDC guidelines would be a

1 significant change in the, in the standard of care.

2 **Q.** And would it be your understanding or opinion that
3 prior to that time when we see fewer of these prescription
4 management tools, that reflects a difference in the standard
5 of care vis-à-vis prescription opioids?

6 **A.** That's a conclusion I would draw, yes.

7 **Q.** Dr. Hughes, are you familiar with alternatives to
8 opioids for the treatment of pain?

9 **A.** Yes.

10 **Q.** And what are some examples of those alternative pain
11 treatments?

12 **A.** Physical therapy, occupational therapy, acupuncture,
13 chiropractic care.

14 **Q.** And have you reviewed literature regarding the extent
15 to which payers covered those kinds of alternative pain
16 treatments --

17 **A.** I have.

18 **Q.** -- as compared to the degree to which they covered
19 prescription opioids for the treatment of pain?

20 **A.** Yes, I have.

21 **Q.** And what did you find?

22 **A.** I found that these alternatives were sometimes not
23 covered. And when they were covered, they tended to have
24 fairly strict limits on, say, the number of visits of
25 physical therapy or the number of visits for chiropractic

1 care and the requirement to obtain prior authorization to
2 obtain additional physical therapy limits.

3 So there was more restrictions put on earlier on these
4 alternative treatments. And Medicaid, for example, doesn't
5 cover acupuncture at all. PEIA covers it, but only in
6 particular circumstances.

7 **Q.** So is it fair to say that the insurance coverage for
8 prescription opioids was more extensive than alternatives
9 for the treatment of pain?

10 **A.** I think that's fair to say, yes.

11 **Q.** And have you looked at this point specifically in West
12 Virginia?

13 **A.** Yes, I have.

14 **Q.** And have you determined whether West Virginia Medicaid,
15 for example, has limits on chiropractic services and
16 physical therapy for the treatment of pain?

17 **A.** They do. There's limits on the number of visits that
18 can be prescribed.

19 **Q.** And you mentioned that West Virginia Medicaid does not
20 cover acupuncture at all?

21 **A.** That's correct. They do not.

22 **Q.** Is West Virginia different from other states, to your
23 experience, in relation to insurance coverage for
24 alternative forms of pain treatment?

25 **A.** Yes, they are different. There are states that, for

1 example, have no quantity limits on physical therapy. There
2 are states that have fairly liberal access to acupuncture.

3 Again, each state sets its own Medicaid rules. And,
4 so, there's a great deal of variation. But there are states
5 that were covered much more, much more easily for the
6 patient to obtain these alternatives compared to West
7 Virginia.

8 **Q.** So, for example, are there other states that cover
9 acupuncture through Medicaid for the treatment of pain? Is
10 that a "yes"? I'm sorry.

11 **A.** I'm sorry. Yes, it is. Sorry.

12 **Q.** Why, why, in your opinion and to your understanding,
13 Dr. Hughes, do payers impose coverage restrictions on these
14 alternative treatments for -- to opioids for the treatment
15 of pain?

16 **A.** It appears to be because these treatments tend to be
17 more expensive. And, so, in an attempt to control costs,
18 they place limits on the availability of those alternative
19 treatments.

20 **Q.** What, if any, impact would you expect to see from the
21 inconsistent or lesser coverage for alternative pain
22 treatments as compared to prescription opioids for the
23 treatment of pain?

24 **A.** Well, I understand that payers consider pain to be a
25 problem. And, so, if the alternatives are not available, I

1 would expect that it would lead, at the margin, to a larger
2 quantity of opioid prescriptions.

3 **Q.** Are you aware of distributors playing any role in
4 payers' decisions about whether to require prior
5 authorization, step therapy, or quantity limits for opioid
6 medications?

7 **A.** No, I'm not.

8 **Q.** Are you aware of distributors playing any role in
9 payers' decisions about whether or how much to cover
10 alternative pain treatments?

11 **A.** No.

12 **Q.** Are you aware of distributors playing any role at all
13 in payers' decisions on coverage for prescription opioids?

14 **A.** No.

15 MR. HESTER: Your Honor, at this point, I pass the
16 witness.

17 THE COURT: It's almost 10 till 5:00. Perhaps we
18 should postpone the cross until tomorrow morning.

19 Is that acceptable to everybody?

20 MR. MAJESTRO: That's fine, Your Honor.

21 MR. HESTER: Well, Your Honor, I don't --

22 MR. MAJESTRO: I can't finish in 10 minutes if
23 that's your question.

24 MR. HESTER: I just wanted to see how long Mr.
25 Majestro thought he would take.

1 MR. MAJESTRO: It's going to be more than 10
2 minutes.

3 THE COURT: You're not going to do it in 10
4 minutes, are you, Mr. Majestro?

5 MR. MAJESTRO: No, Your Honor.

6 MR. HESTER: All right. That's fine, Your Honor.

7 THE COURT: If you could do in 10, we'd finish
8 today.

9 MR. MAJESTRO: Mr. Farrell probably could, but
10 I'm, I'm --

11 THE COURT: Dr. Hughes, I'm going to have to ask
12 you to come back at 9:00 in the morning, sir.

13 THE WITNESS: I'm at your disposal, Your Honor.

14 THE COURT: Thank you. And I'll see everybody at
15 9:00.

16 (Trial recessed at 4:50 p.m.)

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1 CERTIFICATION:

2 I, Ayme A. Cochran, Official Court
3 Reporter, and I, Lisa A. Cook, Official Court Reporter,
4 certify that the foregoing is a correct transcript from
5 the record of proceedings in the matter of The City of
6 Huntington, et al., Plaintiffs vs. AmerisourceBergen
7 Drug Corporation, et al., Defendants, Civil Action No.
8 3:17-cv-01362 and Civil Action No. 3:17-cv-01665, as
9 reported on July 7, 2021.

10
11 S\Ayme A. Cochran

12 Reporter

13 s\Lisa A. Cook

14 Reporter

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16 July 7, 202117 Date
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